No.DCG (I)/MISC/2016 (34)
Directorate General of Health Services
Central Drugs Standards Control Organization
(Office of Drugs Controller General India)

FDA Bhavan, Kotla Road,
New Delhi – 110002.

22nd March, 2016

OFFICE ORDER

As directed by the Ministry of Health & Family Welfare, Government of India the Report of Prof. C.K. Kokate dated 10th February, 2016 on "Evaluation of Cases of Fixed Dose Combinations (FDCs) has been uploaded in the CDSCO website for information.

(Dr. G.N. Singh)
Drugs Controller General (India)

To

All Pharma Associations

Copy to:

(i) PPS to Secretary (H&FW)
(ii) PPS to DGHS
(iii) PPS to Joint Secretary (KLS), MoHFW

To,

10 FEB 2015

The Secretary
Ministry of Health & Family Welfare,
Govt. of India,
Nirman Bhawan, New Delhi-110001.

Subject: **Submission of report by Expert Committee constituted for examination of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)-regarding.**

Sir,

This has reference to Ministry of Health and Family Welfare order No. X11035/53/2014-DFQC dated: 16.09.2014 whereby the Ministry has constituted the Committee under the Chairmanship of Prof. C.K. Kokate, VC, KLE University, Belgaum with the approval of Hon'ble Minister of Health and Family Welfare, Government of India.

The Expert Committee evaluated the replies/clarifications wherever available from firms which were received by CDSCO in response to the showcause notices issued in respect of the FDCs considered as Irrational by the Committee. The Committee also evaluated the earlier data submitted by the firms in respect of such FDCs.

The detailed report alongwith the recommendations of the Committee is enclosed herewith.

We would like to acknowledge with thanks the support received from Dr. G.N. Singh, DCG (I) and his colleagues at CDSCO.

Kokate

(Prof. C.K. Kokate)

REPORT OF EXPERT COMMITTEE

ON

Evaluation of Cases of Fixed Dose Combinations (FDCs) considered as Irrational and where Showcause Notices were Issued to the Applicants for submitting their Replies

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVT. OF INDIA

Date: **Feb.'2016**

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PREFACE

- Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the Chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka for examining the safety and efficacy of unapproved FDCs which were licensed by State Drug Licensing Authorities without due approval of DCG(I).

- After a series of meetings of the Committee, the Committee submitted its first assessment report to the Ministry of Health & Family Welfare on 16.4.2015 categorizing FDCs into Rational, Irrational, Requiring further deliberation and FDCs requiring generation of data. As desired, show-cause notices were issued in respect of FDCs which were considered as Irrational to the concerned manufacturers.

- It was decided that replies received against show-cause notices w.r.t. FDCs considered as Irrational under category 'a' shall be placed before Prof. Kokate Committee for examination. It was decided to examine these FDCs alongwith one expert of Internal Medicine and one relevant subject expert in the respective field, wherever necessary.

- The Committee noted that legacy products are available in the market which were licensed by SLAs without following due procedure as laid down under Drugs and Cosmetics Rules have not been evaluated for their rationality, safety and efficacy which expose patients to unnecessary risk of adverse drug reactions. Further, Injudicious use of antibiotics can lead to resistance which is a serious concern in the country.

- The Expert Committee discussed each FDC in detail and has put its full wisdom in evaluating these FDCs in the interest of public health so that public health of people is not compromised. Committee discussed total

1083 such FDCs. While examining the replies to the Showcause notices of such FDC, Committee considered following points:

a. Patient Safety
b. Drug Toxicity /*Adverse effect*
c. Misuse of drug/ Prescription error
d. Abuse Potential
e. Pharmacokinetic and Pharmacodynamic interaction/*Compatibility*
f. Dosage compatibilities of FDCs vis-a-vis that of single ingredients
g. *Issue of* antimicrobial Drug Resistance
h. Latest Standard Treatment Guidelines (STG)
i. Risk/Benefit ratio
j. Patient Compliance
k. International status

- The detailed recommendations of the Committee have been given against each FDC in the report. The Committee is of the opinion that these FDCs wherever recommended as Irrational should not be allowed for their continued manufacturing and marketing in the country.

(Prof. C.K. Kokate and other members)

Final Recommendations of the Experts Committee during its meetings held w.e.f. 4th to 9th January, 2016 with respect to applications of FDCs received by the O/O DCG(I) for proving safety and efficacy categorized under *category "a"*

S. No. of Main list	Name of FDC	Strength	Dosage Form	Categorization of the FDC by the Experts Committee as per Terms of references	Final Recommendations by Committee
6	Nimesulide BP + Tizanidine HCL IP Eq. to Tizanidine	100mg+2mg	Dispersible tablets	a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule. *Rayasam SP et al., Int J Basic Clin Pharmacol.2013 Aug;2(4) : 452-457.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
10	Aceclofenac IP+Paracetamol IP+Rabeprazole Sodium IP	100mg+325 mg+10mg	Enteric Coated tablets	a, 1.There is pharmacokinetics incompatibility among the three drugs, as the dosing intervals are BD for aceclofenac, OD for rabeprazole and TDS/QID for paracetamol. 2.The FDC is not approved anywhere in the world 3.The literature regarding safety and efficacy of this combination is not available in Pubmed & Google scholar	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
12	Nimesulide BP + Diclofenac Sodium IP	100mg+50 mg	Soft Gelatin Capsules	a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. No additional advantage but hepatotoxic potential of nimesulide and adverse effects add up. 3.Pharmacodynamically irrationale FDC as both have same mechanism of action (both drugs acting on the same enzyme). Thus, combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.* *Kasarla Raju, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
13	Nimesulide BP + Cetirizine HCL IP+Caffeine IP	100mg+5mg+30mg	Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. 2. Nimesulide has documanted safety concern.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

16	Nimesulide +Tizanidine	100mg+2mg	Tablets	a, 1. Nimesulide in combination form has potential of misuse. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule. 3. Safety concern with Nimesulide	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
24	Paracetamol + cetrizine hydrochloride + caffeine (anhydrous)	500mg+ 5 mg+ 15 mg	Tablet	a, 1. Pharmacokinetic incompatibility, as dosing interval for paracetamol is TDS/QID and for cetrizine it is OD/BD. 2. No trial could be found in PUBMED and google scholar. 3. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
29	Cetirizine Hyrochloride IP+ Nimesulide BP+ Paracetamol+ Phenylephrine hydrochloride+ Caffeine	5 mg+ 100 mg+ 325 mg+ 10 mg+ 25 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Nimesulide-safety concern.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
39	Paracetamol IP+Caffeine IP+Phenylepherine HCl	500mg+32 mg+10mg	Tablets	a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

42	Diclofenac Sodium IP + Tramadol HCL BP + Chlorzoxazone USP	50mg+37.5 mg+250mg	film coated tablets	a, 1. Tramadol is an opoid analgesic with abuse liability. 2. The combination will lead to additive sedation. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
43	Dicyclomine HCl IP+Paracetamol IP+Domperidone BP	20mg+500 mg+10mg	Uncoated Bilayered Tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Combining can result in dangerous elevation of the body temperature. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796* *Eccles, R., Fietze, I. and Rose, U.-B. (2014). Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
44	Paracetamol IP+Domperidone Maleate BP Eq. to Domperidone+Dicyclomine HCL IP	500mg+10 mg+10mg	Uncoated Tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Combining can result in dangerous elevation of the body temperature. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796* *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
49	Diclofenac Sodium IP+Paracetamol IP+Magnesium Trisilicate IP+Chlorpheniramine Maleate IP	50mg+325 mg+100mg +4mg	Uncoate Tablets	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

51	Nimesulide BP+Paracetamol IP	100mg/100 mg+500mg/ 325mg	Dispersible tablets/Uncoated tablets	a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. There are safety concerns with nimesuilide FDC with paracetamol. 2. Dose of paracetamol 500mg not approved in FDC with NSAIDs *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
57	Aceclofenac+ Paracetamol+ Rabeprazole	100mg+ 325mg+ 10mg	Capsules	a, 1.There is pharmacokinetics incompatibility among the three drugs, as the dosing intervals are BD for aceclofenac, OD for rabeprazole and TDS/QID for paracetamol. 2.The FDC is not approved anywhere in the world 3.The literature regarding safety and efficacy of this combination is not available in Pubmed & Google scholar	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
58	Nimesulide+ Serratiopeptidase	100mg/100 mg+10mg/15mg	Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
59	Diclofenac sodium+ Paracetamol+ Chlorpheniramine+ Magnesium	50mg+ 500mg+ 4mg+ 100mg	Tablets	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). 2. dose of paracetamol is high. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
62	Tapentadol+Paracetamol	50mg+325 mg	Tablets	This FDC was discussed by previous Committee on 04.06.14- The firm did not turn up for the presentation. The committee noted that the proposal had already been discussed in NDAC on 17.03.2012 and the committee agreed with the recommendations of the NDAC. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

68	Paracetamol + Phenylephrine HCl + Caffeine	500mg +10mg + 32mg	Oral Tablets	a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
74	Diclofenac Sodium+Tramadol HCL+Paracetamol IP	50mg+37.5 mg+325mg	Film Coated Tablets	a, 1.Tramadol is itself a potent opoid analgesic. FDC is not rational as addition of Paracetamol and Diclofenac will not provide any additional benefit.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
82	Diclofenac potassium+ paracetamol + chlorzoxazone + famotidine	50 mg+ 325 mg+ 250 mg+ 20 mg	tablets	a, 1. Pharmacodynamic irrelevant as each ingredient has different dosing shedule/dosing requirement. 2. FDC will lead to misuse and toxicity.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
85	Serratiopeptidase + nimesulide	15 mg+ 100 mg	Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
91	Paracetamol IP+Phenylephrine HCl IP+Caffeine IP	500mg/325 mg+10mg/5 mg+32mg/3 0mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

98	Paracetamol IP + DL-Methionine BP	500mg/650 mg/1000mg /125mg/250 mg/100mg+ 50mg/50mg /100mg/12. 5mg/25mg/ 10mg	Tablets	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
109	Naproxen+Paracetamol IP	300mg/550 mg+325mg	Film Coated Tablets	This FDC was discussed by previous Committee on 04.06.14- There is no scientific justification, the only published literature of this combination has used Paracetamol 4g/day which is much higher than the proposed dose in the FDC. Hence, the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
116	Serratiopeptidase + nimesulide	10 mg+ 100mg	tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
123	Nimesulide + serratiopeptidase	100mg+ 15 mg	film coated tablet	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

133	Paracetamol IP+Diclofenac Potassium BP+Famotidine IP	500mg+50 mg+20mg	Film Coated Tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse. 2. Paracetamol dose is high 3. Both diclofenac and paracetamol hepatotoxic 4. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
149	Tapendole HCL+Paracetamol IP	50mg+325 mg	Film Coated Tablet	This FDC was discussed by previous Committee on 04.06.14- The firm did not turn up for the presentation. The committee noted that the proposal had already been discussed in NDAC on 17.03.2012 and the committee agreed with the recommendations of the NDAC. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
166	Paracetamol IP+Caffeine IP+Codeine Phosphate IP	325mg+15 mg+5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1.Close Monitoring is required as codeine increases and caffeine decreases sedation. 2.Effect of interaction is not clear, Potential for drug drug interaction. 3. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. http://reference.medscape.com/drug-interactionchecker. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

170	Lornoxicam+Paracetamol IP+Serratiopeptidase IP	8mg+325mg+15mg	Tablets	This FDC was discussed by previous Committee on 04.06.14- There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
173	Paracetamol IP+Diclofenac Potassium BP+Famotidine IP	500mg+50mg+20mg	Tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse. 2. Paracetamol dose is high 3. Both diclofenac and paracetamol hepatotoxic 4. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
179	Tramadol hydrochloride + paracetamol+ lornoxicam	37.5 mg+ 325 mg+ 8 mg	film coated bilayered tablet	This FDC was discussed by previous Committee on 04.06.14- The committee opined that you should submit the supporting data of each of the ingredient for each of the indication and also for the combination. If data in support of concomitant use of the three drugs in these indications is found satisfactory, the firm is required to generate the clinical data.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
187	Nimesulide + Pitofenone HCL+ Fenpiverinium bromide + benzyl alcohol	100mg + 2mg + 0.02mg + 4.0%v/v	Injection	a, 1.There are no evidences on safety and efficacy of the FDC. 2. Safety concern with nimesulide	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

199	Omeprazole Magnesium USP eq. to Omeprazole + Paracetamol IP+ Diclofenac Potassium	10mg+ 500mg +50mg	tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse. 2. Paracetamol dose is high 3. Both diclofenac and paracetamol hepatotoxic 4. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
202	Nimesulide BP + Paracetamol IP	30mg+195 mg	Injection	a, 1.There are safety concerns with nimesuilide 2. Both ingredients are hepatotoxic	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
203	Paracetamol IP+Phenylephirine HCl IP+ Caffeine IP+Chlorphenirami ne Maleate IP	500mg+5m g+30mg+4 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
213	Tamsulosin hydrochloride + diclofenac sodium	0.4 mg+ 50 mg	hard gelatin capsules	a; Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

220	Paracetamol IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Caffeine IP	325mg+10 mg+2mg+30mg	Uncoated tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
225	Paracetamol IP+Phenylephirine HCl Ip+Chlorpheniramine Maleate IP+Dextromethorphan Hydrobromide IP+Caffeine IP	650mg+10 mg+4mg+15mg+30mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
232	Diclofenac Potassium BP+Zinc Carnosine	50mg+75mg	Film Coated Tablets	a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
242	Dextromethorphan HBr + paracetamol+ phenyl phrine + chlorpheniramine maleate	15 mg + 650 mg+ 10 mg + 4 mg	uncoated tablet	a, Pharmacodynamically irrelevant - misuse and overuse of one of the ingredient of FDC in case it is not indicated. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
243	dextromethorphan + paracetamol+ phenylphrine+ chlorpheniramine maleate	10 mg+ 250 mg+ 5 mg+ 2 mg	suspension form	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

249	Diclofenac sodium + paracetamol+ chlorpheniramine maleate + magnesium trisillicate	50 mg+ 325 mg+ 4 mg+ 100 mg	tablets	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
250	Paracetamol + pseudoephdrine + cetrizine dihydrochloride	325 mg + 30 mg+ 10 mg	film coated tablet	a, 1. Pharmacokinetic incompatibility, as dosing interval for paracetamol is TDS/QID and for cetrizine it is OD/BD. 2. No trial could be found in PUBMED and google scholar. 3. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
263	Phenylbutazone+Sodium Salicylate	200mg+20 mg	Injection	a, 1.Safety not established and FDC has high risk of toxicity 2. There is no synergism when two drugs acting on the same enzyme are combined. Thus combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects 3. Already prohibited in the country for use in human. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
270	Prochlorperazine Maleate+Paracetamol	5mg+325mg	Tablets	a, Pharmacodynamically irrelevant and under dose of Paracetamol.	c Re-examined the FDC and recommended for use in adult if dose of paracetamol is 500 mg

271	Lornoxicam+Paracetamol+Trypsin	8mg+325mg+150000 AU	Tablets	This FDC was discussed by previous Committee on 04.06.14- There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
281	Nimesulide+Serratiopeptidase	100mg+15 mg	Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
287	Paracetamol IP+Mefenamic Acid IP+Ranitidine HCL+Dicyclomine HCl IP	300mg+100 mg+150mg +10mg	Tablets	This FDC was discussed by previous Committee on 04.06.14- There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
288	Nimesulide BP+Serratiopeptidase IP	100mg+10 mg	Film Coated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

294	Serratiopeptidase IP+Nimesulide BP	15mg+100 mg	Enteric Coated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
298	Nimesulide BP + Pitfenone HCl IP + Fenpiverinium Bromide IP	100mg+3m g+375mg	Injection	a, 1.There are no evidences on safety and efficacy of the FDC. 2. Safety concern with nimesulide	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
306	Nimesulide BP+ Serratiopeptidase IP	100mg+15 mg	Uncoated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
310	Paracetamol IP + Diclofenac Potassium BP + Chlorpheniramine Maleate IP + Magnesium Trisilicate IP	325mg+50 mg+4mg+1 00mg	Uncoated Tablets	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

316	Nimesulide BP + Dicyclomine HCl IP	100mg+20 mg	Uncoated Tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Combining can result in elevation of the body temperature. Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796 Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
326	Paracetamol IP+DL-Methionine	650mg/500 mg/250mg/ 125mg/250 mg/125mg+ 50mg/50mg /25mg/12.5 mg/25mg/1 2.5mg per 5 ml	Tablets and Suspensi on	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
339	Heparin Sodium IP+Diclofenac Sodium IP	200 IU+10mg per gm.	Gel	a, Pharmacodynamically irrelevant- Topical use of heparin is irrelevant.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
342	Glucosamine Sulphate Potassium USP+Methyl Sulfonyl Methane+Vitamin D3 IP+Manganese Sulphate USP eq. to elemental Manganese+Sodium Borate BP eq. to elementaol Boron+Copper Sulpahte USP eq. to elemental Copper+Zinc Sulphate Monohydrate USP eq. to elemental Zinc	750mg+200 mg+200 IU+9.3mg eq. to 3mg+4.4mg eq. to 0.5mg+2.0 mg eq. to 0.5mg+8.24 mg eq. to 3mg	Film Coated Tablets	a, 1. Pharmacodynamic irrelevant as each ingredient has different therapeutic use. 2. therapeutic efficacy of FDC not established and will lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

346	Nimesulide BP+Serratiopeptidase IP	100mg+15 mg	Film Coated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
350	Serratiopeptidase+ Nimesulide BP	10mg+100 mg	Film Coated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
365	Serratiopeptidase IP+Nimesulide BP	15mg+100 mg	Uncoated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
373	Nimesulide BP+Serratiopeptidase IP	100mg+10 mg	Uncoated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

382	Paracetamol IP+Tapentadol HCl	325mg+50 mg	Film Coated Tablets	This FDC was discussed by previous Committee on 04.06.14- The firm did not turn up for the presentation. The committee noted that the proposal had already been discussed in NDAC on 17.03.2012 and the committee agreed with the recommendations of the NDAC. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
386	Tranexamic Acid BP + Proanthocyanidin	250mg+100 mg	Film Coated Tablets	a, Safety and efficacy of Proanthocyanidin in FDC is not established	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
391	Nimesulide+Serratiopeptidase EC	100mg+15 mg	Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
396	Diclofenac Sodium+Paracetamol+Magnesium Trisilicate	50mg+250 mg+100mg	Uncoated tablet	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal) *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
407	Benzoxonium Chloride+Lidocaine HCl	1mg+1mg	Chewable Tablets	a, Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

436	Lornoxicam IP+Paracetamol IP+Tramadol IP	100mg+325 mg+37.5mg	Film Coated tablets	This FDC was discussed by previous Committee on 04.06.14- There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
438	Lornoxicam IP+Paracetamol IP+Serratiopeptidase IP	8mg+325mg+15mg	Film Coated tablets	This FDC was discussed by previous Committee on 04.06.14 as under- There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
440	Diclofenac Sodium IP+Paracetamol IP+Magnesium trisilicate IP	50mg+325 mg+100mg	Uncoated Tablets	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
445	Paracetamol IP+DL-Methionine BP	650mg+50 mg	Uncoated Tablets	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
451	Nimesulide BP+Tizanidine HCl IP	100mg+2mg	Tablets	a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule. *Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug;2(4) : 452-457*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

459	Paracetamol IP+Domperidone IP+Caffeine(Anhydrous) IP	650mg+10 mg+50mg	Uncoated Tablets	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796* *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
477	Nimesulide+Tazanidine HCl	100mg+2mg	Uncoated tablet	a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule. *Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug;2(4) : 452-457*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
481	Ofloxacin+Ornidazole	50mg+125 mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
486	Nimesulide+Diclofenac Sodium	100mg+50 mg	soft gelatine capsules	a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. No additional advantage but hepatotoxic potentia of nimesulide and adverse effects add up. 3.Pharmacodynamically irrationale FDC as both have same mechanism of action (both drugs acting on the same enzyme). Thus, combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.* *Kasarla Raju, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

496	Serratiopeptidase EC+Nimesulide	15mg+100 mg	Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
500	Ammonium Chloride IP+Sodium Citrate IP+Chlorphenirami ne Maleate IP+Menthol IP	100mg+50 mg+4mg+1. 25mg	Oral Liquid	a, 1.Potential of misuse in peadiatric population. 2.Pharmaceutical incompatibility and also the dose of each ingredient is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
502	Paracetamol IP+Prochlorperazin e Maleate IP	325mg+5m g	Uncoated tablet	a, 1. Pharmacodynamically irrelevant and subtherapeutic dose of Paracetamol. 2. Both ingredients have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
504	3 tablets of Serratiopeptidase (enteric coated 20000 units) IP + Diclofenac Potassium BP & 2 tablets of Doxycycline HCL IP	10mg+50m g & 100mg	Kit	a, 1.It will lead to antibiotic resistance. 2. Documented efficacy of Serratiopeptidase not available. 3. May lead to misuse 4. Do not offer any particular advantage over the individual drugs. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
505	Paracetamol IP+Dextromethorp han Hydrobromide IP+Phenylephirine HCl IP+Chlorphenirami ne Maleate IP	325mg+15 mg+5mg+2 mg	Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4.Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

514	Nimesulide BP+Serratiopeptidase IP	100mg+10 mg	Capsules	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
532	Nimesulide BP+Paracetamol IP	50mg+125 mg	Suspension	a, 1.Potential misuse in paediatric population 2.Hepatotoxicity	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
545	Nimesulide BP+Tizanidine HCl IP	100mg+2mg	Film Coated Tablets	a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule. *Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug;2(4) : 452-457*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
559	Nimesulide BP+Dicyclomine Hydrochloride IP	100mg+10 mg/20mg/40mg	Tablet	a, 1.Pharmacodynamic irrelevant as each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Combining can result in elevation of the body temperature. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796* *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

568	Paracetamol IP+DL-Methionine BP	125mg+12.5mg	Uncoated dispersible tablet	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
569	Diclofenac Sodium IP+Paracetamol IP+Magnesium Trisilicate IP	50mg+250mg+125mg	Expectorent (uncoated tablet)	a, 1.Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse and toxicity (hepato and renal). *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
577	Aceclofenac IP+Paracetamol IP+Famotidine IP	100mg+500mg+20mg	Uncoated Tablets	a, 1. Pharmacodynamic irrelevant as each ingredient has different dosing shedule/dosing requirement. 2. FDC will lead to misuse and toxicity.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
578	Aceclofenac IP+Zinc Carnosine	100mg+75mg	Film Coated Tablets	a, There is no therapeutic benefit of adding zinc carnosine in FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
584	Paracetamol IP+DL-Methionine BP	650mg+50mg	Tablet	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

594	Paracetamol IP+Nimesulide BP+Cetirizine Hcl IP+Phenylephrine HclIP+Caffeine Anhydrous IP	325mg+100 mg+5mg+5 mg+25mg	Film Coated Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesulide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
596	Paracetamol IP+ disodium Hydrogen Citrate IP + Caffeine IP	130mg+750 mg+5mg	Oral	a, Pharmacodynamically irrelevant 1. Each ingredient has different therapeutic indication. 2. As Urine alkalizer, patients will be unnecessarily exposed to paracetamol and caffeine.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
598	Paracetamol + DL Methionine BP	125mg+12.5mg	Suspension	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
599	Paracetamol IP+ DL-Methionine BP	125mg+ 12.5mg	Oral Suspension	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

600	Disodium Hydrogen citrate BP+Paracetamol IP	750mg+125 mg	Oral	a, 1:Pharmacodynamically irrelevant combination-each ingredient has different therapeutic indication. 2.As Urine alkalizer, patients will be unnecessarily exposed to paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
602	Paracetamol IP+Di-Sodium Hydrogen Citrate BP	120mg+500 mg	Syrup	a, 1.Pharmacodynamically irrelevant combination-each ingredient has different therapeutic indication. 2.As Urine alkalizer, patients will be unnecessarily exposed to paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
603	Paracetamol IP+Disodium Hydrogen Citrate IP	125mg+500 mg	Syrup	a, 1.Pharmacodynamically irrelevant combination-each ingredient has different therapeutic indication. 2.As Urine alkalizer, patients will be unnecessarily exposed to paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
612	Nimesulide BP+Diclofenac Sodium IP	NA	Uncoated Tablets	a, 1. Nimesulide in combination has potential of misuse and have documanted safety concern. 2. No additional advantage but hepatotoxic potential of nimesulide and adverse effects add up. 3.Pharmacodynamically irrationale FDC as both have same mechanism of action (both drugs acting on the same enzyme). Thus, combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.* *Kasarla Raju, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

625	Aceclofenac IP + Paracetamol IP + Rabeprazole Sodium IP (EC)	100mg+ 325mg +10mg	Film Coated Tablets	a, 1.There is pharmacokinetics incompatibility among the three drugs, as the dosing intervals are BD for aceclofenac, OD for rabeprazole and TDS/QID for paracetamol. 2.The FDC is not approved anywhere in the world 3.The literature regarding safety and efficacy of this combination is not available in Pubmed & Google scholar	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
627	Nimesulide BP+Paracetamol IP+Phenylephirine HCl IP+Cetirizine HCl IP+Caffeine IP	100mg+325 mg+5mg+5 mg+25mg	Uncoated Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
634	Nimesulide BP+Tizanidine HCl IP eq. to Tizanidine	100mg+2m g	Uncoated Bilayered Tablets	a, 1. Nimesulide in combination as a dispersible dosage form has potential of misuse in children. 2. The FDC is pharmacokinetically incompatible as both have different dosing schedule. *Rayasam SP et al. Int J Basic Clin Pharmacol.2013 Aug;2(4) : 452-457*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
635	Nimesulide+Serrati opeptidase	100mg+15 mg	Capsules	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offe any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

645	Paracetamol IP + Caffeine (Anhydrous) IP + Codeine Phosphate IP	325mg+15 mg+5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1.Close Monitoring is required as codeine increases and caffeine decreases sedation. 2.Effect of interaction is not clear, Potential for drug drug interaction. 3. An important safety debate concerning multi-ingredient, multi-symptom relief products for common cold and flu is that they commonly contain paracetamol (acetaminophen) and that users who may not be aware of this may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. *http://reference.medscape.com/drug-interactionchecker.* *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
652	Aceclofenac IP (SR) + Paracetamol IP	200mg+325 mg	Uncoated bilayered modified release tablet	a, 1.Pharmocokinetic incompatibility-dosing shedule of aceclofenac (SR) and paracetamol are of different duration	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
658	Zinc Carnosine+Aceclofenac IP	37.5mg+100mg	Film Coated Tablets	a, There is no therapeutic benefit of adding zinc carnosine in FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
683	Diclofenac Sodium IP+ Paracetamol IP & Inactive Polyethylene Glycol 400 USNF+ Lignocaine HCl IP+ Benzyl Alcohol IP (preservative)+ Sodium Metabisulphate IP	25mg + 75mg & 565.53mg 10mg 1.0% w/v+ 1mg	Injection	a, 1.Hypersensitivity reaction with lignocaine. 2.Paracetamol dose is subtherapeutic which may increase adverse effects (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

684	Azithromycin+Cefixime	250mg/500 mg+200mg/ 200mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
690	Ofloxacin IP+Ornidazole IP	500mg+125 mg per 5ml	Oral suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
697	Amoxicillin Trihydrate IP Eq. to Amoxicillin+Dicloxacillin Sodium USP Eq. to Dicloxacillin	125mg/500 mg+125mg/ 500mg	Tablets/Sachet	Already discussed by previous Committee on 06.03.2014 as under- The committee reviewed following FDC (i) Amoxicillin 250mg + Dicloxacillin 250mg (ii)Amoxicillin 125mg + Dicloxacillin 125mg (iii)Amoxicillin 500mg + Dicloxacillin 500mg It was noted that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in 2006 and the FDC at (ii) and (iii) are nowbeingrequested by the company. Committee opined that : (a) Since, 2006 the scenario of antimicrobial resistance pattern has changed significantly, majority of isolates of Staph. aureus have become resistance to the amoxicillin &cloxacillin including dicloxacillin (b) Better efficacious antibiotic andare now available and used for staph. aureus infections. In light of these, the rationality of combination in current scenario is questionable. It is also noted that this combination is not available anywhere in the world as per information provided by the firm and also the fact that there is only one study presently by the firm showing better efficacy was published in journal "Pharmazie" Sept. 40(9), 650-1, 1984. However after 30 years, this has lost its relevance in today's scenario of drug resistance. Committee therefore doesn't recommended the new strengths of the FDC and also recommended that the superiority of such FDC over the individual drug andneed to be proven in current scenario. Accordingly, Protocol should be submitted within 3 months and data shall be generated within next one and half year. Non- compliance of this instruction may lead to suspension/cancellation of license. (REJECTED)	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

699	Cefixime IP As Trihydrous Eq. to Anhydrous Cefixime+Linezolid	200mg+600 mg	Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
703	Ofloxacin+ Nitazoxanide	50 mg + 100mg	oral liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ofloxacin for indication of nitazoxanide will lead to emergence of antibiotic resistance and serious health care concern.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
713	Cefixime+Azithromycin	100mg+125 mg	Dispersible tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
714	Ornidazole IP+Ofloxacin IP	125.0mg+50.0mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

717	Azitromycin dihydrate IP Eq. to Azithromycin + Ofloxacin IP	500mg+400 mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse in FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
718	Amoxicillin+Potassium Clavulanate Diluted	250mg+62.5mg	Dry Syrup	Already discussed by previous Committee on 06.03.2014 as under- Regarding Amoxycillin 250 mg + clauvulanic Acid 62.5 mg per 5 ml, committee opined that the proposed strength is not recommendable as too many strength will lead to confusion in prescribing for the physician. Hence the committee did not recommend for the proposed strength	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
724	Azithromycin+Levofloxacin	250mg/500 mg+250mg/500mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. The guidelines recommends the use of levofloxacin alon in out patient management of CAP. Hence the committee did not recommend for approval. Levofloxacin is not recommended for MDR typhoid fever, in any of the recommended treatment guidelines. Hence this FDC is not recommended for approval in MDR typhoid fever.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
725	Cefixime+Linezolid	200mg+600 mg	Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Linezolid is a life saving drug to be used for MRSA infection and inappropriate use of linezolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
728	Ofloxacin+Ornidazole	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

729	Cefpodoxime+Levofloxacin	200mg+250mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
734	Cefixime+Azithromycin	200mg+250mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
735	Azithromycin + Ofloxacin	500mg+400mg	Tablets	a, 1Ofloxacin is not safe in children. 2. Increased risk of emergence of drug resistance. 3. Patient may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

736	cefpodoxime proxetil + azithromycin	200 mg+ 250 mg	tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee observed that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
737	Norfloxacin+ metronidazole Benzoate	100mg+ 100mg	liquid suspension	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee observed that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
738	Anhydrous azithromycin + anhydrous levofloxacin	250mg/500 mg+ 250mg/500 mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee observed that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
741	Cefixime+Azithromycin	200mg+250 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee observed that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

742	Cefpodoxime+ Levofloxacin	200mg+250 mg	Film Coated Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
743	Cefpodoxime Proxetil IP eq. to Cefpodoxime+Azithromycin hydrate IP eq. to anhydrous Azithromycin	200mg/200 mg+250mg/ 500mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
744	Azithromycin Dihydrate IP eq. to Azithromycin + Levofloxacin hemi hydrate IP eq .to Levofloxacin	250mg+250 mg	Film Coated Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
745	Cefixime IP (as Trihydrate) Eq. to anhydrous Cefixime+Linezolid IP	200mg+600 mg	Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

746	Ofloxacin +Ornidazole+Lactic Acid Bacillus	200mg+500 mg+2.50 Billion Spores	Tablets	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 3. There is no additional benefit of adding lactic acid bacillus. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	subjudice
747	Cefixime IP+Linezolid IP	200mg+600 mg	Film Coated Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
748	Amoxicillin Trihydrate IP Eq. to Amoxicillin+Cefixime IP as Trihydrate Eq. to Anhydrous Cefixime+Potassium Clavulanic Acid	500mg+200 mg+125mg	Tablets	Already discussed by previous Committee on 06.03.2014 as under- Committee noted that Cefixime requires 12 hourly dosing. Whereas, Amoxicillin dosing schedule is 6-8 hrs. When these two drugs are given in combination, it will have a pharmacokinetic mismatch. As claimed by the firm the dosing of FDC is 12 hourly, which will lead to under dosing of Amoxicillin and may increase possibility of drug resistance. Further the FDC is not approved anywhere in the world. The committee did not recommend for the manufacturing and marketing of the FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
750	Ofloxacin IP+Nitazoxanide	50mg+100 mg	suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of nitrazoxanide will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
751	Ofloxacin IP+Ornidazole IP	50mg+125 mg	suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

753	ofloxacin+ nitazoxanide	50 mg+ 125 mg	suspensio n	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ofloxacin for indication of nitazoxanide will lead to emergence of antibiotic resistance and serious heaith care concern.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
754	cefixine trihydrate + azithromycin dihydrate	200 mg+ 250 mg	tableis	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance: The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
758	cefpodoxine proxetil + levofloxacin hemihydrate	200 mg+ 250 mg	tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
766	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

767	Cefixime+Azithromycin	200mg/200mg/100mg+250mg/500mg/125mg	Film Coated Tablets & Dispersible Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoi fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and availabie peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
768	Cefpodoxime Proxetil+Azithromycin	200mg+250mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
770	Cefpodoxime Proxetil IP eq. to Cefpodoxime+Levofloxacin Hemihydrate IP eq. to Levofloxacin	200mg+250mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

774	azithromycin + levofloxacin	250 mg/500 mg+ 250 mg/500 mg	film coated tablet	Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. The guidelines recommends the use of levofloxacin alone in out patient management of CAP. Hence the committee did not recommend for approval. Levofloxacin is not recommended for MDR typhoid fever, in any of the recommended treatment guidelines. Hence this FDC is not recommended for approval in MDR typhoid fever.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
775	azithromycin dihydrate + secnidazole+ fluconazole	1 g+ 1 g+ 150 mg	tablets (Combikit)	a, 1. Pharmacodynamically irrelevant due to different therapeutic indications of ingredients. FDC may Increase risk of emergence of drug resistance. 2. Patient may require only one ingredient 3. Azithromycin and fluconazole both increase QTc interval, Potential cardiac toxicity. *http://reference.medscape.com/drug-interactionchecker.* 4.The Committee reexamined the combikit of this formulation and it was opined that all the three drugs are not used for same duration in treatment of PID, Vaginal infection.The use of azithromycin is not as per the CDC guidelines (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
780	Oflaxacine IP+Ornidazole IP	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
781	Oflaxacine IP+Ornidazole IP	50mg/125mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

782	Cefixime IP+Azithromycin Dehydrate IP	200mg/250 mg	Oral Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
784	Cefixime IP+Azithromycin Dehydrate IP	200mg/250 mg	Oral Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
786	Norfloxacin+ Metronidazole Benzoate	100mg+150 mg	Suspensi on	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
787	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Syrup	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

790	Levofloxacin+Azithromycin	250mg/500mg+250mg/500mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. The guidelines recommends the use of levofloxacin alone in out patient management of CAP. Hence the committee did not recommend for approval. Levofloxacin is not recommended for MDR typhoid fever, in any of the recommended treatment guidelines. Hence this FDC is not recommended for approval in MDR typhoid fever.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
793	Azithromycin Dihydrate IP eq. to Azithromycin + Neomycin Sulphate IP eq.to Neomycin	300mg+250mg	5gm Intra Mammary Infusion Disposable Syringes	Veterinary FDC - no comments	Veterinary
795	Levofloxacin Hemihydrate IP+Ornidazole IP+Alpha Tocopherol Acetate IP	20mg+40mg+5mg	Solution	a, 1. Patient may need only one ingredient and the use of FDC may lead to misuse. 2. Increased risk of emergence of drug resistance du to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
796	Levofloxacin Hemihydrate IP+Ornidazole IP+Alpha Tocopherol Acetate IP	20mg+25mg+5mg	Clear Solution	a, 1. Patient may need only one ingredient and the use of FDC may lead to misuse. 2. Increased risk of emergence of drug resistance du to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
799	Ofloxacin+Ornidazole	50mg+125mg	Oral suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

801	Amoxycillin Trihydrate+tinidazole	500mg+300 mg	Film coated Tabiet	Already discussed by previous Committee on 06.03.2014 as under- The committee noted that the pharmacokinetics of Amoxicillin require dosing frequency 6-8 hourly In contradiction Tinidazole dosing is twice a day. Further the proposed indications are not as per the clinical indication of these two individual drugs such as Amoebiasis. Tinidazole is good enough for the treatment of amoebiasis and Amoxicillin does not have any role and therefore the FDC does not have any rationale. Even for H. pylori infection the proposed FDC is not rationale. The proposed FDC is also not approved anywhere in the world. Hence the committee didn't recommend the FDC for manufacturing and marketing.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
805	Nimorazole+Ofloxacin	500mg+200 mg	Tablet	a, 1. Patient may need only one ingredient and the use of FDC may lead to misuse. 2. Increased risk of emergence of drug resistance due to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
811	cefixime+ azithromycin	200mg+ 250 mg	tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
812	anhydrous azithromycin + ofloxacin	500m g+ 400 mg	tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increased risk of emergence of drug resistance due to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

815	Fluconazole IP+Azithromycin IP+Secnidazole IP	150mg+1000mg+1000 mg	Kit Tablets	a, 1. Pharmacodynamically irrelevant due to different therapeutic indications of ingredients. FDC may Increase risk of emergence of drug resistance. 2. Patient may require only one ingredient 3. Azithromycin and fluconazole both increase QTc interval, Potential cardiac toxicity. *http://reference.medscape.com/drug-interactionchecker.* 4.The Committee reexamined the combikit of this formulation and it was opined that all the three drug are not used for same duration in treatment of PID, Vaginal infection.The use of azithromycin is not as per the CDC guidelines (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
818	Cefixime Trihydrate IP+Azithromycin Dihydrate IP	200mg+500 mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
819	Cefpodoxime+Azithromycin	200mg+250 mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS)recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

820	Cefpodoxime+Levofloxacin	200mg+250mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
821	Cefixime+Azithromycin	200mg+250mg/500mg	Film coated Bilayered Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
825	Cefpodoxime+Levofloxacin	200mg+250mg	Oral Tablet	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

826	Cefixime + azithromycin	200/200mg +250/500mg	Tablet	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
828	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
829	Azithromycin Dihydrate IP+Cefpodoxime Proxetil IP	250mg/500 mg+200mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
838	amoxycillin trihydrate+ tinidazole	500 mg+ 300 mg	film coated tablet	Already discussed by previous Committee on 06.03.2014 as under- The committee noted that the pharmacokinetics of Amoxicillin require dosing frequency 6-8 hourly. In contradiction Tinidazole dosing is twice a day. Further the proposed indications are not as per the clinical indication of these two individual drugs such as Amoebiasis. Tinidazole is good enough for the treatment of amoebiasis and Amoxicillin does not have any role and therefore the FDC does not have any rationale. Even for H. pylori infection the proposed FDC is not rationale. The proposed FDC is also not approved anywhere in the world. Hence the committee didn't recommend the FDC for manufacturing and marketing.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

839	cefixime+ azithromycin	200mg+ 250 mg	film coated tablet	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
844	Azithromycin +ofloxacin	125mg+50 mg	Suspensi on	a, 1Ofloxacin is not safe in children. 2. Increased risk of emergence of drug resistance. 3. Patient may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
845	Metronidazole benzoate+Norfloxa cin	100mg+100 mg	Suspensi on	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju1, A. Ehmalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
846	Azithromycin+ ofloxacin	250mg+200 mg	Tablet	a, 1.Pharmacodynamically irrelevant FDC. 2. Increased risk of emergence of drug resistance du to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
848	Ornidazole+Ofloxa cin+	125 mg+50mg	Suspensi on/oral liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

852	Cefixime+Levofloxacin Hemihydrate	400mg+500 mg	Tablet	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
857	ofloxacin + beclomethasone dipropionate+ clotrimazole+ lignocaine HCL	0.3% + .025% + 1% + 2%	drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
861	Cefpodoxime+Levofloxacin	200mg+250 mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
862	Praziquantel + Pyrantel Pamoate+ Fenbendazole	50mg +144mg +500mg	Tablets	a, 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Dosing shedule mismatch amongst ingredients.	It is a veterinary drug,not meant for human use.

863	Doxycycline hyclate+Serratiopeptidase	100mg+10mg	Capsule	a, Pharmacodynamically irrelevant- 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
867	Cefixime+Azithromycin	200mg/200mg+250mg/500mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
869	Ofloxacin+Beclomethasone Dipropionate+Clotrimazole+Lignocaine HCL	0.3%w/v+0.025%w/v+1%w/v+2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

876	Cefpodoxine+Azithromycin	100mg+125mg	Dispersible tablet	a, 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse. 3.Azithromycin decreases effects of cefpodoxime by pharmacodynamic antagonism. Significant interaction possible.Bacteriostatic ingredients may inhibit the effects of bactericidal ingredients. *http://reference.medscape.com/drug-interactionchecker.* Already discussed by previous Committee on 11.06.2014 as under-Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
877	Cefpodoxine+Azithromycin	200mg+250mg	Tablets	a, 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse. 3.Azithromycin decreases effects of cefpodoxime by pharmacodynamic antagonism. Significant interaction possible.Bacteriostatic ingredients may inhibit the effects of bactericidal ingredients. *http://reference.medscape.com/drug-interactionchecker.* Already discussed by previous Committee on 11.06.2014 as under-Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
878	Cefixime+Azithromycin	200mg+250mg	Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

879	Cefpodoxime +Azithromycin	320mg+500 mg	Tablets	a, 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse. 3.Azithromycin decreases effects of cefpodoxime by pharmacodynamic antagonism. Significant interaction possible.Bacteriostatic ingredients may inhibit the effects of bactericidal ingredients. *http://reference.medscape.com/drug-interactionchecker.* Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
880	Ofloxacin+Ornidazole	50.0mg+125.0mg	Liquid oral	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
881	Ofloxacin+Ornidazole	50.0mg+125.0mg	Liquid oral	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
882	Ofloxacin+Ornidazole	50.0mg+125.0mg	Liquid oral	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

883	Ofloxacin+Ornidazole	50.0mg125.0mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
885	Norfloxacin IP+Metronidazole Benzoate IP	100mg+100mg	Suspension	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
886	Ofloxacin IP+Ornidazole IP	50mg+125mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
887	Cefixime IP eq. to anhydrous Cefixime+levofloxacin Hemihydrate IP eq. to Levofloxacin	400mg+500mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increased risk of emergence of drug resistance due to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

888	Cefixime+Azithromycin	200mg/200mg+250mg/500mg & 100mg+125mg	Tablets & Dispesible Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
889	Roxithromycin+Serratiopeptidase IP	150mg+10mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.14 as under- The firm did not turn up for presentation. Roxithromycin is an macrolide antibiotic and serratiopeptidase is an proteolytic enzyme having anti-inflammatory effects. The standard treatment guidelines do not recommend such a combination. Hence the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
890	Levofloxacin+Azithromycin	250mg/500mg+250mg/500mg	Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. The guidelines recommends the use of levofloxacin alone in out patient management of CAP. Hence the committee did not recommend for approval. Levofloxacin is not recommended for MDR typhoid fever, in any of the recommended treatment guidelines. Hence this FDC is not recommended for approval in MDR typhoid fever.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
893	Azithromycin IP+Levofloxacin Hemihydrate IP	500mg+250mg/500mg	Film Coated Tablets	a, 1. Pharmacodynamically irrelevant FDC. Increase risk of emergence of drug resistance as patient may need only one ingredient. 2. Azithromycin and levofloxacin both increase QT interval. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

894	Doxycycline HCL IP eq. to Doxycycline anhydrous+Tinidazole IP+Betacyclodextrin USP	100mg+600mg+50mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredients and may lead to misuse 2.There is a risk of antibiotic resistance .	Subjudice
895	Doxycycline HCL IP eq. to Doxycycline anhydrous+Ornidazole IP+Betacyclodextrin USP	100mg+500mg+50mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredients and may lead to misuse 2.There is a risk of antibiotic resistance .	Subjudice
900	Cefixime (As Trihydrate)+Azithromycin Drihydrate IP	200mg+250mg	Film Coated Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Pharmacokinetic incompatibility Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
903	Ofloxacin IP+Metronidazole IP+Zinc Acetate USP	100mg+200mg+10mg	Oral Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of metronidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
906	Norfloxacin IP+Metronidazole IP	200mg+200mg	Tablets	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

908	Ofloxacin IP+nitazoxanide	50mg+100 mg	Oral Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of nitrazoxanide will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
913	Norfloxacin IP + Metronidazole Benzoate IP	100mg+100 mg	Suspension	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
916	Diphenoxylate HCL+Atropine Sulphate+Furazolidone	2.5mg+0.025mg+50mg	Tablets	a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredient which may lead to misuse and adverse effect. 2. Use of two antispasmodic can develop more risk of adverse effect. 3. Use of antibacterial in FDC is irrelevant.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
922	Fluconazole IP Tablets+One Azithromycin Tablets IP+Two Ornidazole Tablets IP	150mg+100mg+750mg	Kit (Film Coated Tablets)	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
923	Norfloxacin IP+Metronidazole Benzoate IP	100mg+120 mg	Suspension	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

924	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
925	Ciprofloxacin HCl IP+Phenazopyridine HCl USP	250mg+200 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- Ciprofloxacin is an antibiotic and phenazopyridine is urinary analgesic for symptomatic relief. Normally ciprofloxacin is used for 5 to 7 days but phenazopyridine is not recommended for more than 2 days due to its serious side effects. Hence, this combination is not rational and the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
926	Ornidazole IP+Ofloxacin IP	125mg+50 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC.as irrational.
929	Ofloxacin IP+Ornidazole IP	200mg+500 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
930	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

933	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
939	Ofloxacin+Ornidazole	50mg+120 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
950	Ofloxacin+Azithromycin Dihydrate	100mg+100 mg	Uncoated dispersible tablet	a, 1Ofloxacin is not safe in children. 2. Increased risk of emergence of drug resistance. 3. Patient may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
957	Cefixime Trihydrate IP eq. to Cefixime+Azithromycin Dihydrate IP eq. to anhydrous Azithromycin	200mg+250 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

959	Cefixime Trihydrate IP eq. to Cefixime+Linezolide IP	200mg+600mg	Film Coated Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
960	Ofloxacin IP+Ornidazole IP	50mg+125mg	Oral Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
965	Cefixime IP eq. to Anhydrous Cefixime+Azithromycin IP eq. to Anhydrous Azithromycin	200mg+250mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
966	Ofloxacin IP+Ornidazole IP	50mg+125mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

969	Cefpodoxime Proetile IP+Azithromycin Dihydrate IP	200mg+250 mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
970	Amoxycillin Trihydrate IP+Dicloxacillin Sodium IP+Serratiopeptidase IP	250mg+250 mg+10mg	Hard gelatin capsules	Already discussed by previous Committee on 06.03.2014 as under- Committee opined that combination of serratiopeptidase with antibiotics has no rationale. Hence Committee didnt recommend for manufacturing and marketing of the proposed FDC (REJECTED)	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
972	Azithromycin Dihydrate IP eq. to Azithromycin+Cefpodoxime Proxetil IP eq. to Cefpodoxime	250mg/500 mg+200mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

973	Cefixime Trihydrate IP+Azithomycin Dihydrate IP	200mg+500 mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
976	Ornidazole IP+Ofloxacin IP	50mg+125 mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
979	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Syrup	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
981	Lignocaine+Clotrimazole+Ofloxacin+Beclomethasone Dipropionate	2%w/v+1%w/v+0.3%w/v+0.025%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

983	Cefixime trihydrate+Azithromycin dihydrate	200mg+250 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
985	Cafuroxime Axetil+ Linezolid	500mg+600 mg	Film Coated Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
986	Cefixime trihydrate+Azithromycin dihydrate	200mg+250 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
987	Cafuroxime Axetil+Linezolid	500mg+600 mg	Film Coated Tablets	a, 1.Use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. 2.Lenizolid is a life saving drug to be used for MRSA infection and inappropriate use of lenizolid can lead to drug resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

989	Ofloxacin+Ornidazole	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
990	Ofloxacin+Ornidazole	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1003	Clobetasol Propionate+Neomycin Sulpahte+Miconazole Nitrate	0.05%w/w+0.1%w/w+2.00%w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
1004	Clobetasol Propionate+Neomycin Sulpahte+Miconazole Nitrate	0.05%w/w+0.5%w/w+2.00%w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
1010	Clobetasol Propioinate BP+Miconazole Nitrate IP+Neomycin Sulphate IP	0.05%w/w + 2.0%w/w + 0.5%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
1021	Ofloxacin IP+Ornidazole IP+Zinc bisglycinate	50mg+125 mg+50mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1026	Norfloxacin IP+Metronidazole	100mg+100 mg	Suspension	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1027	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1028	Levofloxacin Hemihydrate+Azithromycin Dihydrate IP	250mg/500 mg+250mg/ 500mg	Film Coated Tablets	a, 1.Pharmacodynamically irrelevant FDC. 2. Increase risk of emergence of drug resistance due to misuse of FDC . Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. The guidelines recommends the use of levofloxacin alone in out patient management of CAP. Hence the committee did not recommend for approval. Levofloxacin is not recommended for MDR typhoid fever, in any of the recommended treatment guidelines. Hence this FDC is not recommended for approval in MDR typhoid fever.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1030	Norfloxacin IP+Metronidazole IP	400mg+400 mg	Film Coated Tablets	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1038	Metronidazole Benzoate IP eq. to Metronidazole+Nor floxacin IP	100mg+100 mg	Liquid Oral	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. Kasarla Raju1, A. Elumalai2, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1043	Clobetasol+Neomycin+Clotrimazole	0.05%w/w + 0.50%w/w + 1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
1045	Norfloxacin USP+Metronidazole	100mg+100 mg	Liquid Oral	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1055	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1059	Cefixime Trihydrate eq. to Cefixime (Anhydrous) IP+Azithromycin (As Dihydrate) eq. to Azithromycin	200mg+250 mg/500mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1061	Ofloxacin USP+Ornidazole	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1063	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1067	Amoxicillin Trihydrate IP eq. to Amoxicillin+Bromhexine Hydrochloride IP	250mg+8mg	Hard Gelatin Capsule	a, Pharmacodynamically irrelevant- 1. Combining amoxycillin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1068	Cefixime +Azithromycin	200mg+250 mg	Film coated tablet	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1073	Clobetasole Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP	0.05%w/w + 0.5%w/w + 2.00%w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
1075	Ciprofloxacin Hydrochloride IP eq. to Cirofloxacin+Fluticasone Acetonide IP+Clotrimazole IP+Neomycin Sulphate IP	0.5%w/w+ 0.025%w/w + 1.0%w/w + 0.5%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antibiotics , antifungal, steroid in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3.NO study is found supporting the combined use of ingredients in this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1091	Metronidazole IP+Furazolidone IP+ Loperamide IP	1gm+200mg+4mg	Uncoated Tablets	a, 1.antimotility drug will cause toxic megacolon in infective diarrhoea. 2. Loperamide is contra-indicated in infective diarrhea and in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter as it reduces the clearance of pathogens. Hence there is no rationale for combining with antibiotic in an FDC. 3. In bacterial diarrhoea only anti-bacterial drug is effective and antiamoebic drug is useless. Similarly, in intestinal amoebiasis only antiamoebic drug is effective while antibacterial drug is useless. 4.Amoebiasis and bacterial diarrhoea rarely coexist. 5. Only one drug of the combination would be effective and the other one would be useless.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1093	Doxycycline HCl IP eq. to Doxycycline Base+Lacto Acid Bacillus IH	100mg+60 Million spores	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredient and may lead to misuse 2.There is a risk of antibiotic resistance .	Subjudice
1095	Metronidazole IP+Tetracycline HCl IP	300mg+250 mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- May lead to misuse and antibiotic resistance	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1099	Tetracycline HCl IP+Metronidazole IP	333mg+400 mg	Oral Film Coated Tablet	a, Pharmacodynamically irrelevant. 1. Patient may need only one ingredient. 2.Misuse may lead to development of resistance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1100	Ofloxacin USP+ Ornidazole IP	50mg+125 mg	Oral Suspensi on	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1103	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Suspensi on	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1104	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Suspensi on	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1111	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral Liquid	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1112	Cephalexin IP+ Neomycin Sulphate IP+Prednisolone	100mg+100 mg+10mg	Injection	a, Pharmacodynamically irrelevant- 1.May lead to misuse and neomycin is a potent nephrotoxic. It is no longer indicated by parentral route.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1113	Cefpodoxime Proxetil+Levofloxacin Hemihydrate IP	200mg+250 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1114	Cefixime Trihydrate IP+Azithromycin IP	200mg+250 mg/500mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1117	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral Liquid Syrup	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1118	Norfloxacin IP+Metronidazole Benzoate IP	100mg+120 mg	Oral Liquid Syrup	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1122	Doxycycline Hydrochloride IP eq. to Doxycycline+Tinidazole	100mg+300 mg	Film coated tablets	a, Pharmacodynamically irrelevant- 1. Increased risk of emergence of drug resistance. 2. Patient may need only one ingredient and use of FDC may lead to misuse.	Subjudice
1125	Cefpodoxime Proxetil IP eq. to Cefpodoxime+Levofloxacin Hemihydrate IP eq. to Levofloxacin	200mg+250 mg	Film Coated tablets	Already discussed by previous Committee on 11.06.2014 as under- Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1126	Azithromycin (As Dihydrate) IP eq. To Anhydrous Azithromycin + Ambroxol Hydrochloride IP	250mg/500 mg+60mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always do not require an associated dose of mucolytic ingredient. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1127	Azithromycin (As Dihydrate) IP eq. To Anhydrous Azithromycin + Ambroxol Hydrochloride IP	250mg/500 mg+60mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1144	Cefixime trihydrate IP eq. to Cefixime anhydrous+Azithromycin Anhydrous	200mg+250 mg	Film Coated Tablets	Already discussed by previous Committee on 11.06.2014 as under- This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1145	Amoxycillin Trihydrate IP eq. to Amoxicillin+Dicloxacillin Sodium BP eq. to Dicloxacillin	125mg+125 mg	Uncoated dispersible tablets	Already discussed by previous Committee on 06.03.2014 as under- The committee reviewed following FDC (i) Amoxicillin 250mg + Dicloxacillin 250mg (ii)Amoxicillin 125mg + Dicloxacillin 125mg (iii)Amoxicillin 500mg + Dicloxacillin 500mg It was noted that Amoxicillin 250mg + Dicloxacillin 250mg was approved by CDSCO in 2006 and the FDC at (ii) and (iii) are nowbeingrequested by the company. Committee opined that : (a) Since, 2006 the scenario of antimicrobial resistance pattern has changed significantly, majority of isolates of Staph. aureus have become resistance to the amoxicillin &cloxacillin including dicloxacillin (b) Better efficacious antibiotic andare now available and used for staph. aureus infections. In light of these, the rationality of combination in current scenario is questionable. It is also noted that this combination is not available anywhere in the world as per information provided by the firm and also the fact that there is only one study presently by the firm showing better efficacy was published in journal "Pharmazie" Sept. 40(9), 650-1, 1984. However after 30 years, this has lost its relevance in today's scenario of drug resistance. Committee therefore doesn't recommended the new strengths of the FDC and also recommended that the superiority of such FDC over the individual drug andneed to be proven in current scenario. Accordingly, Protocol should be submitted within 3 months and data shall be generated within next one and half year. Non- compliance of this instruction may lead to suspension/cancellation of license. (REJECTED)	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1146	Azithromycin (As Dihydrate) IP eq. To Anhydrous Azithromycin +Ambroxol Hydrochloride IP (In sustained release form)	500mg+60 mg	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1147	Azithromycin (As Dihydrate) IP eq. To Anhydrous Azithromycin +Ambroxol Hydrochloride IP (In sustained release form)	250mg+60 mg	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1. Combining Azithromycin (antibiotic) with other ingredient which has different indication is irrational and will lead to emergence of resistance. 2. There is no justification in combining mucolytic ingredient with antibacterial, as thick secretions in respiratory tract are always not due to respiratory infections. Also the antibacterial therapy always does not require an associated dose of mucolytic ingredient. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. Vol 3|Issue 2| 2013 | 52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1208	cilnidipine + metroprolol succinate + metroprolol tartrate	10 mg+ 47.5 mg+ 50 mg	Tablets	a, Pharmacodynamically irrelevant,there is no scientific justification for two derivatives of metoprolol. Same compound in differerent salt form doit make any pharmacodynamic (Synergistic/additive) hence dose of metoprolol selected in the combination is questionable	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1220	Flunarizine+Elemental Magnesium	10mg+100 mg	Uncoated tablets	a, Pharmacodynamically irrelevant- As there is no published literature supporting use of Elemental Magnesium.	d Re-examined the FDC and Committee recommended for generation of Clinical data in Indian patients.
1229	L-Arginine IP+Sildenafil Citrate IP eq. to Sildanifil	3gm+50mg	Sachet/Film Coated Tablets	a, Pharmacodynamically irrelevant as there is lack of synergism or additive effect and also the dose selection is questionable	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1246	atorvastatin calcium + vitamin D3 + folic acid + vitamin B12 + pyridoxine HCL	5/10/20 mg+ 1000 IU/1000 IU/1000 IU + 2.5 mg/2.5 mg/2.5 mg+ 200 mcg/200 mcg/200 mcg+ 20 mg/20	film coated tablet	a, Pharmacodynamically irrelevant- 1.Atovastatin has definite indication and combining it with vitamins has no additional benefit. 2. Misuse of FDC as vitamin supplement will cause serious adverse effects of atorvastatin.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1257	Metformin+Atorvastatin	1000mg+ 20mg	Tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee opined that there is no advantage of proposed fixed dose combination of atorvastatin and metformin. The dose of atorvastatin depends on the clinical condition and risk factors and accordingly, the dose may range from 10 mg to 80 mg. So the FDC will not be useful in titration of doses. Hence the committee did not recommended the proposed strength.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1270	Clindamycin+Telmisartan	10mg+40mg	Tablet	a, Pharmacodynamically irrelevant- 1. Use of antibiotic with angiotensin receptor blocker is not rational	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1273	Olmesartan+Hydrochlorothiazide IP+Chlorthalidone IP	20mg/40mg +12.5mg+6.25mg	Hard Geletin Capsules	a, 1. Both diuretics present in the FDC have same mechanism of action. 2. Dose trituration will be difficult in FDC. 3. Chlorthalidone will increase the level or effect of hydrochlorothiazide by acidic (anionic) drug competition for renal tubular clearance.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1376	Prochloperazine Maleate + Paracetamol	5mg+ 650 mg	tablet	a, Pharmacodynamically irrelevant and overdose dose of Paracetamol.	c Re-examined the FDC and recommended for use in adult

1379	Betahistine HCl IP+Ginkgo biloba Extract+Vinpocetin +Piracetam	16mg+60mg+5mg+400mg	Tablets	a, Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1390	Promethazine HCl IP+Paracetamol IP	5mg+125mg	Oral Syrup	a, Pharmacodynamically irrelevant 1. Both ingredients have different therapeutic uses.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1396	Phenytoin Sodium+Phenobarbitone	100mg+30mg	Tablets	a, Pharmacodynamically irrelevant. 1. Phenobarbital will decrease the level or effect of phenytoin by affecting hepatic enzyme CYP2C9/10 metabolism. Significant interaction possible. 2. Phenobarbital decreases levels of phenytoin by increasing metabolism. 3. Phenobarbital may occasionally not change or even increase (via competitive inhibition) phenytoin levels. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1397	L-5-Methylterahydrofolate calcium + Escitalopram Oxalate	7.5mg+10mg	Tablets	a, Pharmacodynamically irrelevant- 1. No supporting published literature available on the combination. 2. Both ingredients have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1398	Flupenthixol dihydrochloride+Escitalopram Oxalate	0.5mg+10mg	Tablets	a, Pharmacodynamically irrelevant- 1. No supporting published literature for this FDC. 2. The combination will aggravate the adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1408	Promethazine HCl IP+Pholcodine IP	1.5mg+1.5 mg	Cough Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1409	Promethazine HCl IP+Dextromethorphan Hydrobromide IP	5mg+10mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1413	promethazine HCL+ paracetamol	5 mg + 125 mg	syrup	a, Pharmacodynamically irrelevant 1. Both ingredients have different therapeutic uses.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1414	pholcodine +Promethazine Hydrochloride	1.5mg+1.5 mg	Oral Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1415	Paracetamol IP+Promethazine HCL IP	125mg+5mg	Suspension	a, 1. Pharmacodynamically irrelevant. 2. Both ingredients have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1417	Flupenthixol dihydrochloride+Escitalopram Oxalate	0.5mg+10mg	Tablets	a, Pharmacodynamically irrelevant- 1. No supporting published literature for this FDC. 2. The combination will aggravate the adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1435	Betahistine HCl+Ginkgo Biloba Extract+Vinpocetine+Piracetam	16mg+60mg+5mg+400mg	Film Coated tablets	a, Pharmacodynamic irrelevant - each ingredient has different therapeutic use and FDC will lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1436	Sodium Fluoride IP+Procaine HCl IP	1%w/v + 2% w/v	injection	a,	c. Committee examined the proposal and observed that the product is combikit and is used for elephantoid chages in filariasis
1437	Cetirizine Dihydrochloride IP+Diethyl Carbamazine Citrate IP	5mg+150mg	Tablets	a, 1. Patient may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1459	Doxylamine Succinate+Pyridoxine HCl+Mefenamic Acid+Paracetamol	10mg+50mg+250mg+325mg	Tablets	a, Pharmacodynamically irrelevant- 1. No published literature supporting the FDC. 2. Users who may not be aware of this mefanamic acid content and may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. 3. If misused for morning sickness, it is teratogenic. *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1474	Drotaverine HCl IP + Clidinium Bromide USP + Chlordiazepoxide IP	80mg+2.5mg+5mg	Film Coated Tablets	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1477	Imipramine HCl IP + Diazepam IP	25mg+2mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1482	Imipramine HCl IP + Diazepam IP	25mg+5mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1522	Flupentixol Di-HCl+Escitalopram oxalate	0.5mg+10mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. No supporting published literature for this FDC. 2. The combination will aggravate the adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1530	Imipramine Hcl+diazepam	25mg+2.0mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1537	Pholcodine IP+Promethazine HCl IP	1.5mg+1.5 mg	Liquid Oral	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1542	Flupentixol Dihydrochloride BP eq. to Flupentixol+Melitracen Hydrochloride eq. to Melitracen	0.50mg+10 mg	Film Coated Tablets	a, Already banned	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1546	Paracetamol IP + Prochloperazine Maleate IP	500mg+5mg	Uncoated Tablets	a, 1. Pharmacodynamically irrelevant. 2. Both ingredients have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1548	Imipramine, Chlordiazepoxide, Trifluoperazine & Trihexyphenidyl	25mg+10mg+1.5mg+0.5mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1.Trifluoperazine and imipramine both increase QT interval. 2. High likelihood serious or life-threatening interaction. 3.Trihexyphenidyl and imipramine both decrease cholinergic effects/transmission. 4.chlordiazepoxide and trifluoperazine both increase sedation. 5.Trihexyphenidyl decreases levels of trifluoperazine by pharmacodynamic antagonism. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1550	Paracetamol IP+Promethazine HCl IP	125mg+5mg	Oral Liquid Drop	a, 1. Pharmacodynamically irrelevant. 2. Both ingredients have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1571	Gabapentin USP+Mecobalamin JP+Pyridoxine IP+Thiamine IP	37.5 mg+500mcg+10mg+25mg	Film Coated tablets	a, Pharmacodynamically irrelevant- gabapentin decreases levels of cyanocobalamin by inhibition of GI absorption. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationaliy of this FDC. Hence, the Committee considered this FDC as irrational.
1579	Imipramine Hydrochloride +Chlordiazepoxide IP+Trifluoperazine Hydrochloride IP eq. to Trifluoperazine+Trihexyphenidyl Hydrochloride IP	25mg+10mg+1.5mg+0.5mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1.Trifluoperazine and imipramine both increase QT interval. 2. High likelihood serious or life-threatening interaction. 3.Trihexyphenidyl and imipramine both decrease cholinergic effects/transmission. 4.chlordiazepoxide and trifluoperazine both increase sedation. 5.Trihexyphenidyl decreases levels of trifluoperazine by pharmacodynamic antagonism. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1590	ChlorpromazineHCl IP+Trihexyphenidyl HCl IP	100mg+2mg	Tablets	a, Pharmacodynamically irrelevant- 1.In current scenerio chlorpromazine is not a drug of choice for the treatment of depression. 2. dose adjustment of Trihexyphenidyl to counteract the adverse effect of chlorpromazine is not possible in FDC formulation 3.There is a risk of potential abuse	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1591	Chlopromazine USP+Trihexyphenidyl Hcl IP	200mg+2mg	Tablets	a, Pharmacodynamically irrelevant- 1.In current scenerio chlorpromazine is not a drug of choice for the treatment of depression. 2. dose adjustment of Trihexyphenidyl to counteract the adverse effect of chlorpromazine is not possible in FDC formulation 3.There is a risk of potential abuse	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1601	Glimepiride+Metformin HCl SR	4mg + 1000mg	tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	The Committee re-examined the FDC and recommended for "patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1602	glimepiride+ pioglitazone + metformin	1mg+ 7.5 mg +500 mg	tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1603	Glimepiride IP+pioglitazone+Metformin HCl (as sustainded release)	1mg/2mg+7.5mg/7.5mg +500mg/500mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1605	Ursodeoxycholic Acid + Silymarine	300mg +140mg	Bilayered Tablets	a, Pharmacodynamically irrelevant- 1. UDCA is used for PBC and silymarin is a hepatoprotective. 2. Silymarin does not provide any benefit to patients with Primary Biliary Cirrhosis	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1607	Metformin HCl+Benfotiamine	500mg+75 mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1611	Glimepiride+Metformin HCl	3mg+1000 mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.

1614	Metformin HCL+Pioglitazone HCL + Glimepiride	1000/1000/500/500mg +7.5/7.5/7.5/7.5mg+1/2/1/2mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1615	Metformin HCL+Pioglitazone HCL + Glimepiride	1000/1000/500/500mg +7.5/7.5/7.5/7.5mg+1/2/1/2mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1617	Gliclazide + metformin hydrochloride	80 mg + 325 mg	Tablets	a, Sub-therapeutic dose of metformin.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1618	Glimepiride IP + Metformin HCl (ER)	2mg+850mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1619	Glimepiride IP+Pioglitazone HCl IP+Metformin HCl IP	1mg/2mg+7.5mg/7.5mg+500mg/500mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1621	Glimepiride+Pioglitazone HCl+Metformin HCl	1mg/2mg+7.5mg/7.5mg+500mg/500mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1622	Glimepiride IP+Metformin HCl IP+Pioglitazone HCl IP	2mg+500mg+7.5mg	Uncoated Bilayered tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1623	Glimepiride IP+Pioglitazone HCl IP+Metformin HCl IP	1mg/2mg+7.5mg/7.5mg +1000mg/1000mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1627	Glimepiride IP+Metformin HCl IP+Pioglitazone HCl IP	1mg+500mg+7.5mg	Uncoated bilayered tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1628	Pioglitazone HCl+Metformin HCl+Glimepiride	7.5mg+500 mg+1mg/2 mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1629	Voglibose+ Metformin HCL IP+ Chromium Picolinate USP	0.3mg+850 mg+400mc g	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1.No published literature supporting the superior efficacy of combination of these drugs. 2. Therapeutic use of chromium is doubtfull.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1630	Glimpepiride + pioglitazone HCL+ metformin hydrochloride	1mg/2mg+ 7.5 mg/7.5 mg+ 500 mg/500 mg	tablets	a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1632	Pioglitazone HCL+Metformin HCL	7.5/7.5mg+ 500/1000m g	Bilayed Tablet	a, 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1634	Glimepiride+Pioglitazone HCl+Metformin HCl	1mg/2mg/3mg+15mg+1000mg	Tablets	a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1635	Glimepiride+Metformin HCl	3mg+1000mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1636	Metformin HCL+Benfotiamine	500mg+75mg	Uncoated Tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1637	glimepiride+ pioglitazone hydrochloride + metformin hydrochloride	1mg/2mg+ 15mg/15 mg+ 850 mg/ 850 mg	tablets	a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1638	glimepiride + metformin hydrochloride	3mg/4 mg+ 1000/1000 mg	tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1641	Glimepiride+Pioglitazone HCL+Metformin HCL	1mg/2mg+7.5mg/7.5mg +500mg/500mg	Tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1644	Benfothiamine+Metformin HCl	75mg+500 mg	Tablets	This was discussed by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1645	Pioglitazone HCL+Metformin HCL	7.5mg+500 mg	Tablet	a, 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1650	pioglitazone hydrochloride + metformin hydrochloride.	15 mg+ 850 mg	film coated tablet	a, 1. Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1652	Glimepiride+Metformin HCl	1mg/2mg/3mg+850mg/850mg/850mg	Tablets	The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014.Hence the Committee did not recommend (07.01.2016).	a, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1653	Metformin HCl+Pioglitazone+Glimepride	850mg+7.5 mg+2mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR)+Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1654	Metformin HCl+Glibenclamide	800mg+5mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that FDC of Glibenclamide IP 5mg +Metformin HCl IP 850mg (SR) is already approved. The firm(s) was unable to present any scientific data/evidence in favour of Glibenclamide IP 5mg +Metformin HCl IP 850mg (IR). Also the FDC of Glibenclamide IP 5mg +Metformin HCl IP 800.mg (IR) was also discussed by the committee and the committee opined that there is no unmet need for both the proposed strengths. Hence the committee did not recommend.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1656	Metformin HCl+Pioglitazone HCl+Glimepiride	850mg+7.5 mg+1mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1657	Glimepiride+Metformin HCl	1mg/2mg+850mg/850mg	Tablets	The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014.Hence the Committee did not recommend (07.01.2016).	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1658	Metformin HCL+Pioglitazone HCL + Glimepiride	500mg+7.5 mg+1mg/2 mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

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1659	Metformin HCl+Gliclazide SR+Pioglitazone	500mg+30 mg/60mg+7 .5mg	Tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1662	Voglibose+Pioglitazone+Metformin HCl IP	0.2mg/0.3mg+7.5mg/15mg+500mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of pioglitazone. 2. Safety concerns of pioglitazone. 3. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1663	Metformin HCl IP+bromocriptine Mesylate IP	500mg+0.8 mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. No published literature supporting the use of combination. 2. Both ingredients have different indication.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1667	Benfotiamine+Metformin HCl	75mg+500 mg	Film Coated Tablets	This was discussed by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1670	Metformin HCl IP+Glimepiride IP+Methylcobalamin JP	500mg/500 mg+1mg/2 mg+750mcg/750mcg	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1. No published literature supporting the superior efficacy of combination of three drugs. 2. Use of methylcobalamine as prophylaxis in FDC is not documented.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

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1671	Pioglitazone HCL+Metformin HCl IP	30mg+500 mg	Uncoated Tablets	a, Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1672	Glimepiride IP+Pioglitazone HCl IP+Metformin HCl IP	2mg+30mg +500mg	Uncoated Tablets	a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1677	Glibenclamide+Metformin HCl+Pioglitazone HCl	5mg+500mg+7.5mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm presented two studies, one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. The Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Hence the proposed FDC is not recommended.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1680	Glipizide IP+Metformin HCl IP	2.5mg+400 mg	Uncoated tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The firm could not present any scientific data with respect to the proposed strength of FDC. The committee opined that the proposed strength is not going to add any benefit to the patient over the already approved strengths of the FDC. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1681	Pioglitazone HCL IP+Metformin HCl IP	7.5mg+500 mg/1000mg	Uncoated tablet	a, 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1682	Glimepiride IP+Metformin HCl IP	3mg+1000 mg	Uncoated Bilayered tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1683	Glimepiride IP+Pioglitazone HCl IP+Metformin HCl IP	1mg/2mg+7.5mg+1000 mg	Uncoated Bilayered tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1684	Glimepiride IP+Pioglitazone HCl IP+Metformin Hcl IP	1mg+7.5mg +500mg	Uncoated Bilayered tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1685	Glibenclamide+Metformin HCl	5mg+850mg	Uncoated Tablets	This was discussed by previous Committee on 27.08.14 as under- The committee noted that FDC of Glibenclamide IP 5mg +Metformin HCl IP 850mg (SR) is already approved. The firm(s) was unable to present any scientific data/evidence in favour of Glibenclamide IP 5mg +Metformin HCl IP 850mg (IR). Also the FDC of Glibenclamide IP 5mg +Metformin HCl IP 800mg (IR) was also discussed by the committee and the committee opined that there is no unmet need for both the proposed strengths. Hence the committee did not recommend.	c, The Committee re-examined the FDC and recommended for "non insulin dependent diabites mallitus patients poorly controlled with sulphonylurea or biguanide alone"
1686	Pioglitazone HCL IP+Metformin HCl IP	15mg+850 mg	Uncoated Tablets	a, Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1687	Pioglitazone HCL IP+Metformin HCl IP	7.5mg+500 mg	Uncoated Tablets	a, 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1689	Pioglitazone HCL IP+Metformin HCl IP	7.50mg+1000mg	Uncoated bilayered tablets	a, 1. Subtherapeutic dose of Pioglitazone. 2. Safety issue with Pioglitazone especially as FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1692	Metformin HCl ER+Gliclazide MR+Voglibose	1000mg+60mg+0.2mg	uncoated bilayered tablet	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The firm could not present any scientific data with respect to this FDC. The dosing of voglibose is incompatible with the dosing schedule of metformin ER and gliclazide SR. Hence the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1697	Metformin HCl+Benfotiamine	500mg+75 mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1699	Metformin HCl+Benfotiamine	500mg+75 mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1706	Glimepiride IP+Metformin Hydrochloride IP	3mg/4mg+1 000mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for "patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.

1707	Metformin Hydrochloride IP+Benfotiamine	500mg+75 mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1708	Chromium Polynicotinate+Metformin Hydrochloride IP	200mcg+500mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1.No published literature supporting the superior efficacy of combination of these drugs. 2.There is a controversy regarding the use of chromium.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1709	Metformin Hydrochlopride IP+Gliclazide IP+Piogllitazone Hydrochloride IP eq. to Pioglitazone+Chromium Polynicotinate	500mg+80 mg+15mg+ 200mcg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns. 3. It is at variance from the concept and purpose of FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1710	Metformin Hydrochloride IP+Gliclazide IP+Chromium Polynicotinate	500mg+80 mg+200mcg	Uncoated Tablet	a, Pharmacodynamically irrelevant- 1. No published literature is available supporting the superior efficacy of combination of three drugs 2. there is a controversy regarding the use of chromium.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1718	Glimepiride IP+Metformin Hydrochloride IP (in sustained release form)	3mg/4mg+1000mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1719	Glimepiride IP+Metformin Hydrochloride IP (in sustained release form)	3mg/4mg+1000mg	Film Coated Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients And further permutation of the combination of this FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.	c, The Committee re-examined the FDC and recommended for"patients with type II diabetes mellitus when diet exercise & single agent does not result in adequate glycemic control.
1720	Metformin Hydrochloride IP (SR)+Pioglitazone Hydrochloride+Glimipride	500mg+7.5mg+1	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1723	Metformin hydrochloride IP+Benfotiamine	500mg+75 mg	Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1724	Glibenclamide IP+ Metformin Hydrochloride IP(SR)+ Pioglitazone Hydrchloride IP eq. to Pioglitazone	5mg+500m g+15mg	Uncoated Bilayered tablets	a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1727	Glimepiride IP+Metformin Hydrochloride IP (in sustained release form)+Pioglitazone Hydrochloride IP eq. to Pioglitazone	1mg/2mg+5 00mg+7.5m g	Uncoated bilayered tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1728	Glimepiride IP+Metformin Hydrochloride IP (in sustained release form)+Pioglitazone Hydrochloride IP eq. to Pioglitazone	1mg/2mg+500mg+7.5mg	Uncoated bilayered tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1729	Metformin hydrochloride IP (sustained released Form)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepiride IP	1000mg+7.5mg+1mg	Uncoated bilayered tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1731	Metformin Hydrochloride IP (sustainded release)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepride IP	500mg+15mg+3mg	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns. 3. It is at variance from the concept and purpose of FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1732	Metformin Hydrochloride IP (sustainded release)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepride IP	1000mg+15mg+1mg	Uncoated bilayered tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns. 3. It is at variance from the concept and purpose of FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1733	Metformin Hydrochloride IP (sustainded release)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepride IP	1000mg+7.5mg+2mg	Uncoated bilayered tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1735	Metformin Hydrochloride IP (SR)+Pioglitazone Hydrochloride IP+Glimipride IP	500mg+7.5 mg+1mg	Uncoated Bilayered Tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1736	Metformin Hydrochloride IP (SR)+Pioglitazone Hydrochloride IP eq. To Pioglitazone	500mg+7.5 mg	Uncoated Bilayered Tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Pioglitazone. 2. Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1737	Metformin Hydrochloride IP (SR)+Pioglitazone Hydrochloride eq. to Pioglitazone IP+Glimipride IP	500mg+7.5 mg+2mg	Uncoated Bilayered Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1738	Metformin Hcl IP(SR)+Glibenclamide Ip+Pioglitazone HCl IP eq. to Pioglitazone	500mg+5mg+7.5mg	Uncoated Bilayered Tablets	This FDC was discussed earlier by previous Committee on 27.08.14 as under- The usual dose of pioglitazone is 15 mg. Firm presented two studies, one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. The Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Hence the proposed FDC is not recommended.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1739	Chloramphenicol IP+Beclomethasone Dipropionate IP+Clomitrimazole IP+Lignocaine HCl IP	5% w/v + 0.025% w/v + 1% w/v + 2% w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1740	Ofloxacin IP+Beclomethazone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP	0.3% w/v + 0.025% w/v + 1% w/v + 2% w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1741	Ofloxacin+Beclomethasone Dipropionate + Clotrimazole+ Lignocaine HCl	0.3%w/v + 0.025% w/v + 1% w/v + 2% w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1742	Clotrimazole + Ofloxaxin + Lignocaine + glycerine and propylene glycol	1%w/v+ 0.3w/v + 2% w/v + q.s	Ear drops	a; Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal,in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1743	Clotrimazole + Ofloxaxin +Beclomethasone Dipropionate+ Lignocaine + glycerine and propylene glycol	1% w/v+ 0.3% w/v+ 0.025%w/v +2%w/v q.s	otobiotic Plus ear drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1749	Ofloxacin+Beclomethasone Dipropionate+Clotrimazole+Lignocaine HCl	0.3%w/v+0.025%w/v+1.0%w/v+2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1753	Ofloxacin+Beclomethasone Dipropionate+Clotrimazole+Lignocaine HCL in Glycerine & Propylene Glyco	0.3%w/v+0.025%w/v+1%w/v+2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1756	Chloramphenicol+ Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP in Glycerine IP & Propylene Glycol IP	5% w/v + 0.025% w/v + 1% w/v + 2% w/v	Ear drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1760	Chloramphenicol+ Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP+Propylene Glycol IP & Glycerin IP	5.0%w/v + 0.025%w/v + 1.0%w/v + 2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1761	ofloxacin + beclomethasone+ clotrimazole + lignocaine hydrochloride + glycerine + propylene glycol	.3%w/v + .025% w/v + 1% w/v + 2% w/v	ear drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1762	ofloxacin+ clotrimazole+ beclomethasone dipropionate+lignocaine hydrochloride	0.3% w/v + 1.0% w/v+ .025%w/v + 2.0%w/v	ear drops	a; Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1763	Ofloxacin+beclomethasone dipropropionate+Clotrimazole+Lignocaine HCL	0.3%w/v+0.025%w/v+1%w/v+2%w/v	Ear drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence o resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages funga growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1767	Clotrimazole IP+Ofloxacin IP+Betamethasone Dipropionate USP+Lignocaine HCl IP	1%w/v + 0.3%w/v + 0.025%w/v + 2%	Ear drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence o resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages funga growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1780	Chloramphennicol+Lignocain+Betamethasone+Clotrimazole+Ofloxacin+Antipyrine	5% / 5% / + 2% / 2% / 2% / 1.4% + 0.025% / 0.025% + 1% / 1% + 0.3% + 5.4%	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence o resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages funga growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1783	Chloramphenicol IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lidocaine BP	5%w/v + 0.025%w/v + 1%w/v + 1.73%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence o resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages funga growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lidocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1786	Ofloxacin IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP	0.3%w/v + 0.025%w/v + 1.0%w/v + 0.2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1789	Ofloxacin IP+Clotrimazole IP+Betamethasone Dipropionate USP+Lignocaine HCl IP	0.3%w/v + 1.0%w/v + 0.025%w/v + 2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1791	Gentamicin Sulphate IP+Clotrimazole IP+Betamethasone Dipropionate USP+Lignocaine HCl IP	0.3%w/v + 1.0%w/v + 0.025%w/v + 2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1793	Ofloxacin IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP	0.3%w/v + 0.025%w/v + 1.0%w/v + 2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1798	Ofloxacin+Beclomethasone Dipropinate+Clotrimazole+Lignocaine HCl	0.3%w/v+0.025%w/v+1.0%w/v+2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1806	Lidocaine BP+Clotrimazole IP+Ofloxacin IP+Beclomethasone Dipropionate IP	1.73%w/v + 1.00%w/v + 0.30%w/v + 0.025%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lidocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1807	Chloramphenicol+Beclomethasone Dipropionate+Clotrimazole+Lidocaine HCl	5%w/v+0.25%w/v + 1.0%w/v + 1.73%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lidocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1810	Beclomethasone Dipropionate IP+Chloramphenicol IP+Clotrimazole IP+Lignocaine HCl IP	0.025%w/v + 5%w/v + 1%w/v+ 2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1811	Clotrimazole IP+Beclomethasone Dipropionate IP+Ofloxacin IP+Lignocaine HCl IP	1%w/v + 0.025%w/v + 0.3%w/v + 2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1812	Beclomethasone Dipropionate IP+Clotrimazole IP+Chloramphenicol IP+Lignocaine HCl IP	0.025%w/v + 1%w/v + 5%w/v + 2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1814	Chloramphenicol+ Beclomethasone Dipropionate+Clotrimazole+Lignocaine HCl	5%w/v+0.025%w/v+1%w/v+2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1816	Becloemthasone Dipropionate+Clotrimazole+Chloramphenicol+Gentamycin Sulpahte+Lignocaine Hcl	0.025%w/v+1%w/v+5%w/v+0.3%w/v+2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1817	Clotrimazole+Beclomethasone Dipropionate+Ofloxacin+Lignocaine HCl	1%w/v+0.025%w/v+0.3%w/v+2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1818	Ofloxacin IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine HCl IP	0.3%w/v + 0.025%w/v + 1.0%w/v + 0.2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1823	Clotrimazole IP+Ofloxacin IP+Beclomethasone Dipropionate IP+Lignocaine HCl IP	1% + 0.30% + 0.03% + 2%	Ear drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1833	Flunarizine dihydrochoride + Paracetamole+ Domperidone +Maleate	5mg+ 500mg+ 10 mg	Tablet	a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1836	Rabeprazole sodium + cinitrapride hydrgen tartrate	20 mg+ 3 mg	tablets	a,	c Re-examined and recommended for "the treatment of patients suffering from gasteroesophageal reflux disease (GERD)".

1842	Flunarizine dihydrochoride + Paracetamole+ Domperidone	5mg+325mg+10mg	Tablets	a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1847	Zinc Carnosine+Diclofenac Potassium BP	37.5mg+50 mg	Tablets	a, There is no therapeutic benefit of adding zinc carnosine in FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1850	Rabeprazole Sodium IP+Zinc carnosine	20mg+75mg	Capsules	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1874	magaldrate + famotidine + simethicone	400 mg+ 10 mg+25 mg	tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of Famotidine. 2. No evidence of efficacy exists supporting the use of triple drug combination.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1876	cyproheptadine + thiamine citrate	2mg+ 275 mg	syrup	a, 1. Pharmacodynamically irrelevant. 2..No publish literature is available to support the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1877	Ranitidine HCl IP eq. to Ranitidine+ Magaldrate IP	150mg+200 mg	Fim Coated Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1878	Magaldrate IP+Ranitidine +Pancreatin Ip+Domperidone IP	400mg+150 mg+125mg +10mg	Tablets	a, Pharmacodynamically irrelevant- 1. There is no use of combining an antiemetic ingredient (domperidone) with drugs for peptic ulcer as vomiting may not always be associated with it. 2. Pharmacokinetic incompatibility.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1880	Rabeprazole Sodium IP+Zinc Carnosine	20mg+150 mg	Hard Gelatin Capsule	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1912	Ranitidine HCL IP+Magaldrate IP+simethicone IP	150mg+200 mg+20mg	Film Coated Tablet	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1914	Flunarizine+Dompe ridone+Paracetamo	5mg+10mg +325mg	Tablet	a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

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1929	rabeprazole sodium+ zinc carnosine	20 mg+ 75 mg	film caoted tablet	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1934	magaldrate + papain+ fungul diastase + simethicone	400 mg+ 60mg+ 20 mg+ 25 mg	film coated tablet	a, Pharmacodynamically irrelevant- 1. Papain and fungal diastase are digestive enzymes. Simethicone an anti foaming ingredient is used to reduce bloating sensation due to excessive gas production. 2. No published literature supporting the mechanism of action or efficacy for the combination is available. 3.Use of Magaldrate is not justified (08.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1944	Rabeprazole sodium+ zinc carnosine+ domperidone	20 mg+ 75 mg/37.5 mg+ 10 mg/20 mg	hard gelatin capsules	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1945	Rabeprazole sodium+ zinc carnosine	20 mg+ 75 mg	hard gelatin capsules	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1954	Famotidine BP+ oxytacaine BP+ Magaldrate IP	20mg+5mg +400mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1962	Aluminium Hydroxide+Magnesium hydroxide+activated dimethicone+sorbitol solution	300mg+250mg+40mg+1000mg	liquid oral	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- Committee was not in favour of FDCs with sorbitol as one of the ingredients, as sorbitol (particularly in last few years) has been shown to exacerbate the symptoms of functional gastrointestinal disorders and sorbitol restriction is advised in the patients suffering from these diseases as per published data. Hence the committee did not recommend its inclusion in these FDCs.	c Replies /clarification recieved from the firms were examined.It was noted that similar FDC is already approved by DCG(I) .The addition of sorbitol in the current strength is within the safe limit.Committee opined FDC should be indicated for "hyperacidity with flatulence".
1964	Ranitidine+Domperidone+Semithicone	150mg+10mg+20mg	Tablet	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1966	Rabeprazole sodium+domperidone+zinc sulphate	20mg+30mg+75mg	Capsule	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1973	Alginic Acid+Sodium Bicarbonate+Dried Aluminium Hydroxide+Magnesium Hydroxide	200mg+70mg+300mg+150mg	oral	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- The committee opined that internationally there is no authentic reference for inclusion of sodium bicarbonate in a combined antacid formulation. Sodium bicarbonate is a systemic alkalinizer and not a locally acting antacid. There is risk of systemic adverse effects on chronic use of such products. Hence the committee did not recommend such FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
1974	Alginic Acid+Sodium Bicarbonate+Dried Aluminium Hydroxide+Magnesium Hydroxide	200mg+70mg+150mg+75mg	Chewable Tablets	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- The committee opined that internationally there is no authentic reference for inclusion of sodium bicarbonate in a combined antacid formulation. Sodium bicarbonate is a systemic alkalinizer and not a locally acting antacid. There is risk of systemic adverse effects on chronic use of such products. Hence the committee did not recommend such FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1982	Activated Dimethicone+Magnesium Hydroxide+Dried Aluminium Hydroxide+Sorbitaol Solution (70%) Non-Crystallizing	50mg+250mg+250mg+0.650gm	Oral Liquid	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- Committee was not in favour of FDCs with sorbitol as one of the ingredients, as sorbitol (particularly in last few years) has been shown to exacerbate the symptoms of functional gastrointestinal disorders and sorbitol restriction is advised in the patients suffering from these diseases as per published data. Hence the committee did not recommend its inclusion in these FDCs.	c Replies /clarification recieved from the firms were examined.It was noted that similar FDC is already approved by DCG(I) .The addition of sorbitol in the current strength is within the safe limit.Committee opined FDC should be indicated for "hyperacidity with flatulence".
2013	Clidinium Bromide USP+Paracetamol IP+Dicyclomine HCl IP+Activated Dimethicone IP	2.5mg+500mg+10mg+25mg	Uncoated Tablets	a, Pharmacodynamic irrelevant- 1.Each ingredients have different therapeutic use an FDC will lead to misuse. 2.Pain of petic ulcer is not due to spasm and hence there is no rationale for combining with dicyclomine	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2034	Furazolidone IP+Metronidazole IP+Loperamide HCl IP	500mg+100 0mg+7.5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1.antimotility drug will cause toxic megacolon in infective diarrhoea. 2. Loperamide is contra-indicated in infective diarrhea and in patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter as it reduces the clearance of pathogens. Hence there is no rationale for combining with antibiotic in an FDC. 3. In bacterial diarrhoea only anti-bacterial drug is effective and antiamoebic drug is useless. Similarly, in intestinal amoebiasis only antiamoebic drug is effective while antibacterial drug is useless. 4.Amoebiasis and bacterial diarrhoea rarely coexist. 5. Only one drug of the combination would be effective and the other one would be useless.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2037	Aluminium Hydroxide Paste IP+Magnesium Hydroxide Paste IP+Activated Dimethicone IP+Sorbitol Solution	300mg+200mg+125mg+750mg	Syrup	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- Committee was not in favour of FDCs with sorbitol as one of the ingredients, as sorbitol (particularly in last few years) has been shown to exacerbate the symptoms of functional gastrointestinal disorders and sorbitol restriction is advised in the patients suffering from these diseases as per published data. Hence the committee did not recommend its inclusion in these FDCs.	c Replies /clarification recieved from the firms were examined.It was noted that similar FDC is already approved by DCG(I) .The addition of sorbitol in the current strength is within the safe limit.Committee opined FDC should be indicated for "hyperacidity with flatulence".
2075	Rabeprazole Sodium IP+Diclofenac Potassium BP+Paracetamol IP	10mg+50mg+325mg	Hard gelatin capsules	a, 1.Pharmacokinetic/Pharmacodynamic incompatibility. 2.Subtherapeutic dose of rabeprazole. 3.No published literature support combination of rabeprazole with diclofenac and paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2082	Activated Dimethicone IP+Magnesium Hydroxide IP+Dried Aluminium Hydroxide Gel IP+Sorbitol Solution	50mg+250 mg+250mg +1.25gm	Suspensi on	This FDC was earlier discussed by previous Committee on 05.09.2014 as under- Committee was not in favour of FDCs with sorbitol as one of the ingredients, as sorbitol (particularly in last few years) has been shown to exacerbate the symptoms of functional gastrointestinal disorders and sorbitol restriction is advised in the patients sufferin from these diseases as per published data. Hence the committee did not recommend its inclusion in these FDCs.	c Replies /clarification recieved from the firms were examined.It was noted that this FDC is already approved by DCG(I) .The addition of sorbitol in the current strength is within the safe limit.Committee opined FDC should be indicated for "hyperacidity with flatulence".
2099	Ranitidine HCl Ip+Magaldrate IP	300mg+200 mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2114	Ranitidine HCl+Magaldrate	150mg+200 mg	Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2120	Rabeprazole Sodium IP+Domperidone IP+Zinc Carnosine	20mg+30m g+75mg	Hard gelatin capsules	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2124	Paracetamol IP+Domperidone IP+Flunarizine HCl IP	325mg+10 mg+5mg	Tablets	a, Pharmacodynamically irrelevant- 1. Indication for each drug is different. 2. There is no common condition in which all three drugs are useful. 3. In case of migraine, flunarizine is used for prophylaxis, whereas paracetamol and domperidone are used for acute attack treatment.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2130	Norfloxacin+ Metronidazole Benzoate + zinc Acetate	100mg+200 mg+10mg	oral suspensio n	a, 1.FDCs of quinolones and nitroimidazoles (e.g. norfloxacin + metronidazole, ciprofloxacin + tinidazole, ofloxacin + ornidazole) have not been recommended in children. 2.This FDC can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. *Kasarla Raju, A. Elumalai, Eddla Srid. IRRATIONAL DRUG COMBINATIONS. 2013;3(2):52-56.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2141	Pancreatin IP+Activated Dimethicone IP	170mg+80 mg	Enteric Coated Tablets	a, 1. Pharmacokinetic incompatibility. 2. Pancreatin is made up of the pancreatic enzymes trypsin, amylase, and lipase. Dimethicone is antiflatulent. No published literature supports the use of combination	d The enzymetic activity of pancreatin in presence of Dimethicone is not established as per current literature,same needs to be established.
2142	Zinc Carnosine+Rabepra zole Sodium IP+Domperidone IP	75mg+20m g+30mg	Hard Gelatin Capsules	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC. 2. Fdc will enhance the risk of adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2143	Zinc Carnosine+Pantopr azole sodium	75mg+40m g	Hard gelatin capsules	a, Pharmacodynamically irrelevant- I. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2161	Zinc Carnosine+Oxetaca ine BP	50mg+10m g	Liquid	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2167	Diethyl Carbamazine Citrate IP+Chlorpheniramine Maleate IP+Guaiphenesin IP	100mg+2mg+60mg	Film Coated Tablets	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2168	Oxetacaine BP+Magaldrate IP+Famotidine IP	5mg+400mg+20mg	Uncoated Tablet	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2169	Zinc Carnosine+Sucralfate USP	75mg+500mg	Uncoated Tablet	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2230	Mebeverine Hydrochloride IP+Streptococcus faecalis T-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus	135mg+60 Million+4 Million+2 Million+100 Million	Capsules(Powder for inhalation)	a, Pharmacodynamically irrelevant- 1. No published literature supporting the use of combination. 2. Mebeverine is used for relieving spasm in treatment of irritable bowel syndrome (IBS) and the associated abdominal cramping. 3. Therapeutic indication of Mebeverine and Probiotic are different.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2239	Pantoprazole Sodium sesquihydrate eq. to Pantoprazole (as EC Tablet)+Zinc Carnosine (as FC Tablets)	40mg+75mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2240	Pantoprazole Sodium sesquihydrate eq. to Pantoprazole (as EC Tablet)+Zinc Carnosine (as FC Tablets)	40mg+75mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2241	Pantoprazole Sodium sesquihydrate eq. to Pantoprazole (as EC Tablet)+Zinc Carnosine (as FC Tablets)	40mg+75mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- No published literature supporting the FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2249	Rabeprazole Sodium IP+Domperidone IP+Zinc Carnosine	20mg+30mg+37.5mg	Hard Gelatin Capsules	a, Pharmacodynamically irrelevant- 1.No published literature supporting the FDC. 2.Potential for adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2251	Zinc Carnosine+MagnesiumHydroxide IP+Dried Aluminium Hydroxide IP+Simethicone IP	50mg+250mg+250mg+50mg	Oral Liquid - Suspension	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2252	Zinc Carnosine+Sucralfate IP	50mg+500mg	Oral Liquid - Suspension	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2253	Zinc Carnosine+Oxetacaine BP	50mg+10mg	Oral Liquid - Suspension	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2255	Zinc Carnosine+Pantoprazole Sodium sesquihydrate IP eq. to Pantoprazole(as enteric coated tablets)	75mg+40mg	Film coated Tablets	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2256	Zinc Carnosine+Sucralfate USP	75mg+500 mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. No published literature supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2274	Mebeverine Hydrochloride IP & Inner HPMC capsule (Streptococcus Faecalis T-110 JPC+Clostridium butyricum TO-A+Bacillus mesentricus TO-A JPC+Lactic Acid Bacillus)	135mg+60 Million+4 Million+2 Million+ 100 Million	capsules	a, Pharmacodynamically irrelevant- 1. No published literature supporting the use of combination. 2. Mebeverine is used for relieving spasm in treatment of irritable bowel syndrome (IBS) and the associated abdominal cramping. 3. Therapeutic indication of Mebeverine and Probiotic are different.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2281	Clindamycin Phosphate BP Eq. to Clindamycin+Clotrimazole IP+Lactic Acid Bacillus	100mg+200 mg+1.5 Billion Spores	Soft Gelatin veginal	This FDC was discussed by previous Committee on 22.08.2014 as under- Committee opined that the FDC is not rational. As firm did not present any evidence with regards to its superiority and further drug resistant lactic acid bacillus spores in this combination may spread community drug resistance. Hence, the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2317	Sildenafil Citrate eq. to Sildenafil+Estradiol Valerate	25mg+1mg	Tablets	a, Pharmacodynamically irrelevant- 1. Both ingredients have different indications. 2. No clinical studies are found supporting this combination.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2323	Clomifene Citrate IP+Ubidecarenone USP+Zinc Sulphate IP+Folic Acid IP+Methylcobalamin JP+Pyridoxine Hydrochloride IP+Lycopene USP+Selenium+Levocarnitine Tartrate+L-Arginine USP	25mg+60mg+66mg+5mg+1500mcg+1.5mg+4mg+200mcg+50mg+20mg	Film coated Tablets	a, 1.No published literature supporting this combination of a ovulation inducing ingredient(clomiphene) with multivitamins and antioxidants. 2.Clomifene is used for only five days . Others drugs like folic acid ,Lycopene etc.need to be used for at least two month prior to clomifene therapy (07.01.2016)	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2334	Dehydroepiandrosterone (DHEA) (micronized)+Calcium Carbonate IP eq. to elemental Calcium+Cholecalciferol IP+Methylcobalamin+L-Methylfolate Calcium+PyridoxL 5 Phosphate	50mg+500mg+2000IU+1500mcg+1mg+0.6mg	Film Coated Tablets	a, 1. Pharmacodynamically irrelevant. 2. No published literature supporting this combination of DHEA with multivitamins and minerals	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
2336	Thyroxine Sodium IP Eq. to 0.045 mg of anhydrous thyroxine sodium+Pyridoxine Hydrochloride IP+Folic Acid IP	0.05mg+1mg+1.5mg	Oral Tablet	a, No clinical studies found supporting the use of this combination	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2431	Gentamycin+Dexamethasone+Chloramphenicol+Tobramycin+Ofloxacin	0.3%+0.1%/0.1%/0.1%/0.1%+0.5%+0.3%+0.3%	Eye drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2493	Enrofloxacin+Bromhexine HCl	200mg+15 mg per ml	Oral Solution	a, Pharmacodynamically irrelevant- 1.Enrofloxacin is not approved for human use.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2497	Dextromethorphan Hydrobromide IP+Bromhexine HCl+Menthol IP+Ammonium Chloiride IP	5mg+4mg+ 2.5mg+50m g/5ml	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2503	Dextromethorphan Hydrobromide+ Levocetirizine Hcl IP+Phenylephrine Hcl IP+Zinc Gluconate USP Eq. to Elemental Zinc	10mg+2.5m g+5mg+7.5 mg per 5ml	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere wit the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2504	Diphenhydramine Hcl IP+Guaiphenesin IP+Bromhexine HCl IP+Ammonium Chloride IPMenthol IP	8mg+50mg +100mg+1 mg per 5ml	Syrup	a, Pharmacodynamically irrelevant. • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2505	Nimesulide BP+Loratadine USP+Phenylephrin e HCl IP+Ambroxol HCl	100mg+2.5 mg10mg+1 5mg	Tablets	a, Pharmacodynamic irrelevant- 1.Each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Pharmacokinetic mismatch. *Chandler S. Gautam, Lckha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796* *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2507	Paracetamol IP+Guaiphenesin IP+Ambroxol HCl IP+Phenylephrine HCl IP+Chlorpheniramine Maleate	325mg+100mg+30mg+10mg+2mg	Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2510	Ambroxol Hcl IP+Guaiphenesin IP+Chlorpheniramine Maleate IP+Phenylephirine HCl IP+Menthol IP	15mg+50mg+2mg+5mg+1mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2511	Paracetamol IP+Phenylephrine HCl IP+Ambroxol HCl IP+Chlorpheniramine Maleate	125mg+2.5mg+7.5mg+1.0mg	Oral Drops	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Potential for drug-drug interaction. 4.Dosing shedule of the ingredients is incompatible. 5.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2513	Paracetamol IP+Ambroxol HCl IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+15mg+5mg+2mg	Oral Syrup	a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2514	Bromhexine HCl IP+Phenylephrine HCl IP+Chlorepheniram ine Maleate IP	4mg+5mg+2mg	Oral Solution	a, Pharmacodynamically irrelevant- 1.chlorpheniramine + phenylephrine chlorpheniramine increases and phenylephrine decreases sedation. Effect of interaction is not clear, use caution. 2.Dosing shedule of the ingredients are not compatible	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2516	Dextromethorphan Hydrobromide+ bromhexine hydrochloride+Guaiphenesin	10mg+ 2 mg+ 100mg	Soft gel capsule	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2518	Levocetirizine Hydrochloride + Paracetamol + caffeine (anhydrous)+ Phenylephrine Hydrochloride	2.5mg+ 500mg+ 15 mg+ 10 mg	tablet	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2520	Paracetamol + Loratadine + phenylephrine Hydrochloride + Dextromethorphan Hydrochloride + caffeine	325mg+ 3.3 mg+ 10 mg+ 10 mg+ 30 mg	Tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2521	Nimesulide + Phenylephrine hydrochloride + Ceffeine(anhydrous) + levocetirizine Dihydrous	100mg+ 10 mg+ 30 mg+ 5 mg	Tablet	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3. Nimesuilide- Safety concern	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2527	Azithromycin IP as dihydrate eq to Anhydrous Azithromycin+ acebrophyline	250 mg /50 mg + 100mg/ 100mg	tablet	a, 1. Pharmacodynamically irrelevant-combining anti-bacterial with bronchodialator is not indicated. 2. Potential misuse as bronchodialator with anti-bacterial will increase the emergence of drug resistance to azithromycin and its adverse effects .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2528	Dextromethorphan Hydrobromide + Paracetamol + clorpheniramine Maleate + phenylephrine hydrochloride	5mg+ 125 mg+ 1 mg+ 5 mg	oral syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2531	ambroxol hydrochloride + guaiphenesin Ip+ phenylepherine Hydrochloride + chlorpheniramine maleate + menthol flavoured	15 mg+ 50 mg + 5 mg+ 2mg +	Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2536	Levoctirizine HCL IP+Paracetamol IP+Phenylephrine HCL IP+Caffeine (anhydrous) IP	2.5mg+325 mg+10mg+ 15mg	Tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3. Subtherapeutic dose of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2542	Levocetrizine HCl+Phenylephrine HCl+Paracetamol IP+Caffeine	2.5mg+10m g+500mg+3 0mg	Tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2543	Paracetamol IP+Cetirizine HCL IP+Phenylephrine HCl IP+Zinc Gluconate USP Eq. to Elemental Zinc	250mg+2.5 mg+5.0mg+ 26.14mg eq. to 3.75mg	Suspensi on	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2545	Dextromethorphan Hydrobromide IP+Tripolidine HCL IP+Phenylephrine HCl IP	10mg+1.25 mg+5mg	Syrup	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2547	Dextromethorphan Hydrobromide IP+Chlorphenirami ne Maleate IP	10mg+4mg	Syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)
2548	Diphenhydramine HCl IP+Terpine Hydrate USP+Ammonium Chloride IP+Sodium Chloride IP+Menthol IP	12.5mg+7.5 mg+125mg +55mg+1.5 mg	Oral Liquid	a, Pharmacodynamically irrelevant. No published literature supporting the combination	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2549	Paracetamol IP+Phenylephrine HCl IP+Chlorphenirami ne Maleate IP+Caffeine IP	500mg+5m g+4mg+30 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2550	Paracetamol IP+Phenylephrine HCl IP+Chlorphenirami ne Maleate IP+Caffeine IP	5mg+325m g+2mg+30 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2553	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP+Caffeine IP	500mg+10 mg+5mg+3 0mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2558	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Caffeine IP	500mg/500 mg+2mg/2 mg+10mg/5 mg+30mg/3 0mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2560	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate+Caffeine	500mg+10 mg+2mg+3 0mg	Tablets	a; 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2563	Ambroxol HCl+Levocetrizine Di-HCl+Phenylephrine HCl+Guaiphenesin	15mg+0.8m g+5mg+50 mg	Oral Liquid	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2565	Dextromethorphan HCL+Bromhexine HCL+Guaphensin+Chlorpheniramine Maleate	10mg+8mg +100mg+2 mg	Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2566	Nimesulide+Paracetamol+Cetrizine HCl+Phenylephrine HCL	100mg+325mg+5mg+5mg	Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2578	Paracetamol+Phenylepherine+Caffeine+Levocetirizine	500mg+10mg+30mg+2.5mg	Tabelts	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2579	Salbutamol Sulphate+ Etofylline HCl+Bromhexine HCl	1mg+50mg+4mg	Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2583	bromhexine HCL +guaiphenesin +phenylephrine HCL +chlorpheniramine maleate +paracetamol IP and paracetamol IP + chlorpheniramine maleate +bromhexine HCL+ guaiphenesin IP++phenylephrine HCL	8mg/8mg/8mg+100mg/50mg/50mg+5mg/5mg/5mg+2mg/4mg/2mg+325mg/325mg/325mg	film coated tablet/uncoated tablet	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3.Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2584	Paracetamol+Phenylephrine HCL+Cetirizine HCL+Caffeine	500mg/500mg/325mg+10mg/10mg/10mg+2.5mg/5mg/5mg+30mg/30mg/30mg	Film coated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2586	Levocetirizine HCL+ Paracetamol+Caffeine+ Phenylephrine HCL	5mg/2.5mg/2.5mg+500mg/325mg/500mg+30mg/30mg/15mg+5mg/10mg/2.5mg	Tablets	a, Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2588	Phenylephrine HCL+Chlorpheniramine Maleate+Caffeine (Anhydrous)	10mg+2mg+30mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2591	paracetamol + chlorpheniramine maleate + phenylephrine Hcl + caffiene	650 mg+ 2 mg+ 10 mg + 30 mg	tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2592	paracetamol + cetirizine hydrochloride + dextromethorphan hydrochloride + pseudoephedrine hydrochloride	250 mg+ 2.5 mg+ 5 mg+ 15 mg	syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaninic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2593	paracetamol+ loratadine + dextromethophan + pseudoepheridine HCL + caffeine	650 mg+ 3.3. mg+ 10 mg+ 60 mg+ 30 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2596	chlorpheniramine maleate+ dextromethophan+ dextromethophan HBr + guaiphenesin + ammonium chloride + menthol	2.5 mg+ 5mg+ 50 mg+ 60 mg+ 1 mg	Syrup	This FDC was discussed earlier on 23.04.2014 by previous Committee and their comments are as under- The committee carefully examined the composition of each FDC, their indications as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observes the following: 1. The products of agenda 1 and 2 combines expectorants and cough suppressants. Thus the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient. 2. The products of agenda 3 and 4 contain actives like levocetrizine (anti-histamine), phenylephrine (decongestant), ambroxol (mucolytic-expectorant) and paracetamol; the indications are dry cough, allergic rhinitis, body ache and fever, upper respiratory affections etc. The medical rationale for combining these actives is inadequate and the FDCs tend to accommodate diverse types of patient situations and symptoms which usually do not co-exist. Thus a clear identifiable patient group for the FDC's was missing. 3. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 4. There is also apparent lack of pharmacokinetic and pharmacodynamic compatibility - while levocetrizine is usually given once a day, phenylephrine or ambroxol would require more frequent administration. Use of Paracetamol in some of the referred FDC's seems un- warranted, not to speak of the strength of the Paracetamol used (325 mg), which seems inadequate to treat fever or body-ache in adult subjects. 5. Safety & Efficacy: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 6. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 7. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2597	Ambroxol HCL + guaiphenesin+ Phenylephrine HCL + chloroheniramine Maleate + menthol	15 mg+ 50 mg+ 10 mg+ 2 mg+ 1 mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2598	paracetamol + levocetrizine Di HC Phenylephrine HCL + Caffeine Anhydrous	325 mg+ 2 .5 mg+ 5 mg+ 30 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2599	chlorpheniramine maleate + ammonium chloride + sodium citarte+	2.5 mg+ 125 mg+ 55 mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2600	chlorpheniramine maleate + dextromethophan hydrobromide	4 mg+ 10 mg	syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)
2604	Ambroxol HCl IP+Levocetirizine HCl IP+Guaiphenesin+ Phenylephrine HCl IP+Menthol IP	15mg+0.8mg+50mg+5 mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may no need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2606	Paracetamol+Phenylphrine HCl IP+Chlorpheniramine Maleate IP+Caffeine	325mg+10 mg+4mg+20mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2608	Bromhexine HCl IP+Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Guaiphenesin IP	8mg+650mg+5mg+2mg+50mg	Uncoated tablets	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucu secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3.Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility 4.Over dose and misuse of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2610	Paracetamol IP+Levocetirizine HCl IP+Phenylephrine HCL IP+Ambroxol HCl IP	500mg/325 mg+2.5mg/ 5mg+5mg/5 mg+60mg/3 0mg	Tablets	This FDC was deceased earlier on 23.04.2014 by previous Committee and their comments are as under- The committee carefully examined the composition of each FDC, their indications as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observes the following: 1. The products of agenda 1 and 2 combines expectorants and cough suppressants. But the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient. 2. The products of agenda 3 and 4 contain actives like levocetirizine ;anti-histamine), phenylephrine (decongestant), ambroxol (mucolytic-expectorant) and paracetamol; the indication are dry cough, allergic rhinitis, body ache and fever, upper respiratory affections etc. The medical rationale for combining these actives is inadequate and the FDCs tend to accommodate diverse types of patient situations and symptoms which usually do not co-exist. Thus a clear identifiable patient group for the FDCs was missing. 3. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 4. There is also apparent lack of pharmacokinetic and pharmacodynamic compatibility - while levocetirizine is usually given once a day, phenylephrine or ambroxol would require more frequent administration. Use of Paracetamol in some of the referred FDCs seems un- warranted, not to speak of the strength of the Paracetamol used (325 mg), which seems inadequate to treat fever or body-ache in adult subjects. 5. Safety & Efficacy: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 6. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 7. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2611	Nimesulide BP+Paracetamol IP+Cetirizine HCl IP+Phenylephrine HCl IP+Caffeine IP	100mg/100 mg+325mg/ 325mg+5m g/5mg+10m g/5mg+25m g/25mg	Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2612	Chlorpheniramine Maleate+Ammoniu m Chloride+Sodium Citrate	4mg+125m g+65mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2616	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP+Caffeine IP	325mg+10 mg+2mg+3 0mg	Uncoated tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2617	Cetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP+Zinc Gluconate	5mg+5mg+325mg+52.25mg+7.5mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2626	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg/4mg/4mg+10mg/10mg/10mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2628	Paracetamol BP+Chlorpheniramine Maleate BP+Phenylephrine BP+Caffeine Anhydrous BP	500mg+2mg+10mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2630	Dextromethorphan Hydrobromide+Cetirizine HCl+Zinc+Menthol	7.5m+2.5mg+7.5mg+1.5mg	Syrup	1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2632	Ambroxol HCl IP+Guaiphenesin IP+Ammonium Chloride IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Menthol IP	15mg+50mg+100mg+2.5mg+2mg+0.1mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2637	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP+Caffeine IP	650mg+10 mg+5mg+2 5mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2638	cetirizine hydrochloride+ paracetamol + phenylephrine hydrochloride + caffeine (anhydrous)	5 mg+ 650 mg+ 10 mg + 30 mg	tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2640	cetirizine hydrochloride+ paracetamol+ phenylephrine HCl+ zinc gluconate	2.5 mg+ 125 mg+ 2 5 mg+ 3.75 mg	syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2642	dextromethophen HBr + bromhexine hydrochloride + chlorpheniramine maleate + guaiphenesin	10 mg+ 8 mg+ 2 mg + 100 mg	tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2644	Paracetamol+ Phenylephrine hydrochloride + Chlorpheniramine maleate + Caffiene	325mg + 10 mg + 2 mg + 30 mg	uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2646	enrofloxacin + bromhexin hydrochloride + glacial acetic acid + polysorbate + 2-pyrrolidinone	200mg + 15 mg	injection	a, Pharmacodynamically irrelevant- 1.Enrofloxacin is not approved for human use.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2648	dextromethophen HBr + bromhexine hydrochloride + chlorpheniramine maleate + guaiphenesin	10mg+ 8 mg+ 2 mg+ 100 mg	tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2650	levocetirizine dihydrochloride + ambroxol hydrochloride + phenylephrine hydrochloride +guaiphenesin	0.8 mg+ 15 mg+ 5 mg+ 50 mg	syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2654	dextromethophen HBr + chlorpheniramine hydrochloride + chlorpheniramine maleate +	15 mg+ 5 mg+ 2 mg	syrup	a	composition appears to be wrong.
2655	cetirizine Di HCL+ ambroxol HCL+ Guaiphenesin + ammonium chloride+ phenylephrineHCL + menthol	2.5 mg+ 30 mg+ 50 mg+ 100 mg+ 5 mg+ 1 mg	syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2658	codiene phasphate+ chlorpheniramine maleate	10 mg+ 4 mg	oral liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2659	chlorpheniramine Maleate + phenylephrine HCL+ caffiene	500mg+ 2 mg+ 10 mg+ 30 mg	uncoated tablet	a, 1.Pharmacodynamically irrationale FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2660	dextromethorphan + triprolidine + phenylephrine	10 mg+ 1.25 mg+ 5 mg	oral liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2662	Terpinhydrate+ dextromethorphan HBr+ menthol	10 mg+ 10 mg+ 3.75 mg	liquid oral dosage	a, Pharmacodynamically irrelevant. No published literature supporting the combination.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2664	dextromethorphan HCL+ phenylephrine HCL+ zinc gluconate+ mentho	2.5 mg+ 5 mg+ 2.5 mg+ 7 .5 mg+ 2.5 mg	syrup	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2665	chlorpheniramine Maleate+ codeine phosphate + sodium citarte + menthol	2 mg+ 10 mg+ 1.5 mg+ 1.5 mg	oral liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2666	paracetamol + phenylephrine HCL+ chlorpheniramine Maleate + caffeine	325mg+ 10 mg+ 2 mg+ 30 mg	tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2671	Codeine Phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Oral Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2672	Enrofloxacin + bromhexin hydrochloride	100mg+7.5 mg	Solution	a, Pharmacodynamically irrelevant- 1. Enrofloxacin is not approved for human use.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2673	Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Menthol IP	4mg+5mg+ 5mg+2.5mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2676	Levofloxacin Hemihydrate IP+Bromhexine HCl IP	100mg+7.5 mg	Solution	a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredient and the use of FDC may lead to misuse. 2. Increased risk of emergence of drug resistance due to misuse of FDC .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2678	Levocetirizine HCl IP+Ranitidine HCl IP	5mg+150m g	Film Coated Tablets	a, Pharmacodynamically irrelevant as both ingredients are indicated for different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2682	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP+Dextromethorp han Hydrobromide IP+Caffeine IP	650mg+5m g+5mg+10 mg+30mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2687	Bromhexine Hcl IP+Dextromethorp han Hydrobromide IP+Ammonium Chloride IP	4mg+5mg+ 50mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2688	Levocetirizine HCl IP+Phenylephrine HCl IP+Ambroxol IP+Guaiphenesin IP+Paracetamol IP	2.5mg+10m g+60mg+10 0mg+325m g	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3.Potential drug interactions.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2689	Dextromethorphan Hydrobromide+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	10mg+5mg+2mg	Syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)
2690	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Caffeine IP	500mg+2mg+5mg+16 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2695	cetirizine hydrochloride+ dextromethorphan hydrobromide+ phenylephrine hydrochloride + zinc gluconate + paracetamol+ menthol	2.5 mg+ 7.5 mg+ 5mg+7.5 mg+ 125 mg+ 2.5 mg	60 ml syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2696	paracetamol+ pseudoephedrine hydrochloride + dextromethorphan hydrobromide+ cetirizine hrdrochloride	500mg+ 60 mg+10 mg+ 5mg	tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2700	dextromethorphan+ cetirizine HCL+ phenylephrine+ menthol	5 mg + 2.5 mg+ 5.0 mg+ 1 mg	syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2701	diphenhydamine HCL+ guaiphenesin + ammonium chloride + bromhexine HCL	8 mg+ 50 mg+ 100 mg+ 4 mg + 1 mg	syrup	a, Pharmacodynamically irrelevant. • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2702	cetirizine hydrochloride+ phenylephrine HCl+ paracetamol+ Nimusulide+ caffiene	5 mg+ 10 mg+ 325mg+ 100 mg+ 25 mg	tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Nimesulide-safety concern.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2703	chlorpheniramine maleate + codiene phosphate	4 mg+ 10 mg	syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2708	Chlorpheniramine Maleate +Dextromethorphan Hydrobromide +Phenylephrine HCL+Paracetamol	2mg+10mg +5mg250mg	Oral Liquid Suspension	a, 1 Dosing schedule is incompatible. 2.Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2709	Dextromethorphen HBr IP+Promethazine HCL IP	15mg+5mg	oral liquid (syrup)	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2710	Paracetamol+Phenylephrine HCL+Chlorpheniramine Maleate + caffeine	500/500/325/325/325mg+5/5/5/10/10/10mg+2/2/2/4/2/4mg+15/20/30/16/30/15mg	Tablet	a, 1.Pharmacodynamically and pharmacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2711	Diethylcabamazine citrate IP+Cetrizine HCL IP +Guaiphenesin IP	100mg+3.33mg+50mg	Tablet	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2712	Pseudoephedrine+ Dextromethorphan HBr+Cetirizine HCL	60mg+10mg+5mg	Tablet	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2716	Paracetamol+Chlorpheniramine Maleate+Phenylephrine HCL+Caffeine	250mg+1mg+5mg+15mg	Tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2718	Paracetamol IP+Guaiphenesin IP+Ambroxol HCl IP+Phenylepherine HCl IP+Chlorpheniramin Maleate	325mg+100mg+30mg+10mg+2mg	Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2719	Ambroxol HCl IP+Guaiphenesin IP+Ammonium Chloride IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Menthol IP	15mg+50mg+100mg+2.5mg+2mg+0.1mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2721	Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine IP+Paracetamol IP	5mg+2mg+20mg/30mg+325mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2722	Dextromethorphan Hydrobromide+Guaiphenesin IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	10mg+100mg+5mg+4mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2725	Phenylephrine HCl IP+Triprolidine HCl IP	5mg+0.625mg	Syrup	a,	c Recommended for the treatment of common cold and cough
2726	Bromhexine HCl IP+Dextromethorphan Hydrobromide+Ammonium Chloride+Menthol IP	4mg+5mg+50mg+2.5mg per 5ml	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2727	Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Dextromethophan Hydrobromide IP+Menthol IP	2mg+5mg+10mg+0.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2728	Ambroxol HCl IP+ Terbutaline Sulphate IP+ Dextromethorphan Hydrobromide IP	15mg+1.25 mg+7.5mg	Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drug is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2729	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaiphenesin IP	10mg+4mg +100mg per 5ml	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2730	Terbutaline Sulphate+Bromhexine HCl+Guaiphenesin +Dextromethorphan Hydrobromide	2.5mg+8mg +100mg+10 mg	Uncoated tablets	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2733	Dextromethorphan Hydrobromide IP+Tripolidine HCL IP+Phenylephirine HCl IP	10mg+1.25 mg+5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2734	Paracetamol IP+Dextromethorphan Hydrobromide+Chlorpheniramine Maleate IP	125mg+5mg+1mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2735	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg+10mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2738	Codeine Phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2745	Pholcodine+Phenylephrine HCL+Promethazine HCL	1.5mg+2.5mg+1.5mg	Oral Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2746	Bromhexine HCL+Dextromethorphan HBr+Ammonium Chloride+Menthol	4.0mg+5mg+50mg+2.5mg	Liquid Dosage Form	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2752	Bromhexine hydrochloride + Phenylephrine hydrochloride+ Guaiphenesin + Chlorpheniramine maleate+ Paracetamol	8 mg + 5 mg+ 100 mg+ 2 mg+ 325 mg	tablets	a, Pharmacodynamically irrelevant- 1. Bromhexine ;a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2755	dextromethorphan + chlorpheniramine	10 mg + 4 mg	oral liquid	a	C Inadvertatntly included as "a". Same is approved by DCG(I)
2757	codeine phosphate+ levocetirizine HCL + menthol	10 mg+ 1.67 mg+ .1 mg	syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4.There is also a risk of abuse potential.	The replies/clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2759	Paracetamol+Phenylephrine HCL+Dextromethorphan Hydrobromide+Caffeine+Chlorampheniramine Maleate	500mg+5mg+10mg+25mg+2mg	Tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies/clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2760	Nimesulide+paracetamol+cetirizine HCL+Phenylephrine HCL+Caffeine	100mg+325mg+5mg+2.5mg	Tablet	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies/clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2761	nimesulide+loratadine+Ambroxol HCL+Phenyleprine HCL	100mg+5mg+30mg+20mg	Tablet	a, Pharmacodynamic irrelevant- 1.Each ingredient has different therapeutic use and FDC will lead to misuse and toxicity. 2. Pharmacokinetic mismatch. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796* *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies/clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2766	Nimesulide+paracetamol+cetirizine HCL+Phenylphrine +caffeine anhydrous	100mg+325 mg+5mg+10mg+25mg	Tablet	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2767	Cetrizine HCL+Dextromethorphan HBr++Acetaminophen+Phenylephrine HCL+zinc gluconate+Menthol	2.5mg+7.5 mg+125mg +5mg+7.5mg+2.5mg	Syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2768	paracetamol+ phenylephrine hydrochloride+ chlorpheniramine maleate + caffeine	650 mg+ 10 mg+ 4 mg+ 30 mg	tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2771	chlorpheniramine maleate+ codeine phosphate	4 mg+ 10 mg	liquid oral dose	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2772	paracetamol + phenylephrine hydrochloride + caffeine+ chlorpheniramine maleate	500 mg+ 10 mg+ 30 mg+ 2mg	uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2777	dext. omethorphan HBR+ ambroxol hydrochloride + guaifenesin + phenylephrine hydrochloride+ chlorpheniramine maleate	10 mg+ 15 mg+ 100 mg+ 10 mg+ 2 mg	uncoated tablet	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2784	Cetirizine HCl IP+Phenylephrine HCL IP+ Dextromethorphan Hydrobromide IP+ Menthol IP	5mg+ 5mg+ 10mg+ 1.5mg	syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2785	Roxithromycin IP+ Serratiopeptidase	150mg+10 mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- May lead to misuse and drug resistance	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2786	Paracetamol IP+Phenylephrine HCl IP+Triprolidine HCl IP	325mg+5mg+2.5mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2789	Montelukast Sodium IP+Levocetirizine Dihydrochloride IP+Acibrophyllin	10mg+5mg +200mg	Film coated Tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty:	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2791	Bromohexine HCL+Dextrometho rphan hydrobromide+Am monium chloride+menthol	4mg+5mg+ 50mg+2.5m g	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2792	Acetaminophen+Lo ratadine+ambroxol HCL+Phenylephrin e HCL	325mg+5m g+30mg+20 mg	Tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2793	Cetirizine HCL+Acetaminoph en+Dextromethorp han HBr+Phenyephrine HCL+Zinc gluconate	5mg+325m g+15mg+5 mg+7.5mg	Tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2798	diethylcarbamazine citrate+ cetirizine hydrochloride + guaifenesin	150 mg+ 5 mg+ 100 mg	film coated tablet	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2800	Dextromethophan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaiphenesin IP+Ammonium Chloride IP	5mg+2.5mg+50mg+60mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centraily acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2802	Diphenhydramine HCL IP+Guaifenesin IP+Bromhexine HCl IP+Ammonium Chloride IP+Menthol IP	8mg+50mg+4mg+100mg+1mg	Syrup	a, Pharmacodynamically irrelevant. • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2804	Chlorpheniramine Maleate IP+ Ammonium Chloride IP+ Sodium Citrate IP+Menthol IP	4mg+100mg+40mg+1mg	Cough Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2805	Chlopheniramine Maleate+Codeine Phosphate	4mg+10mg	Liquid Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2808	Cetirizine HCl IP+Dextromethorphan Hydrobromide IP+Zinc Gluconate +Menthol IP	2.5mg+5mg+7.5mg+2.5mg	Oral Liquid	a, Pharmacodynamically irrelevant. 1.Patients may need only one ingredient and use of FDC may lead to misuse. 2..Pharmacokinetic incompatibility amongst ingredients. 3..Use of anti-histamine with centrally acting anti-tussive ingredient is not rationale	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2809	Paracetamol IP+Phenylephrine HCl IP+Desloratadine+ Zinc Gluconate USP+Ambroxol HCl IP	250mg+5.0 mg+1.25mg +10.0mg+1 5mg	Suspensi on	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2810	Levocetirizine Dihydrochloride+P aracetamol+Phenyl ephrine HCL+Caffeine IP	2.5mg+325 mg+10mg+ 15mg	Film Coated Tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2816	Paracetamol IP+Caffeine IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP	325mg/325 mg+16mg/3 0mg+1.5mg /2mg+5mg/ 10mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2820	levocetirizine HCL+ montelukast + acebrophylline	5mg + 10 mg+ 200 mg	tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2822	dextromethorphan hydrobromide + phenylephrine HCl+ ammonium chloride _ menthol	5 mg+ 5 mg+ 50 mg+ 2.5 mg	syrup	This FDC was discussed earlier on 23.04.2014 by previous Committee and their comments are as under- The committee carefully examined the composition of each FDC, their indications as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observes the following: 1. The products of agenda 1 and 2 combines expectorants and cough suppressants. Thus the product does not target an identified – patient group. The medical rationale for combining the actives is insufficient. 2. The products of agenda 3 and 4 contain actives like levocetrizine (anti-histamine), phenylephrine (decongestant), ambroxol (mucolytic-expectorant) and paracetamol; the indication are dry cough, allergic rhinitis, body ache and fever, upper respiratory affections etc. The medical rationale for combining these actives is inadequate and the FDCs tend to accommodate diverse types of patient situations and symptoms which usually do not co-exist. Thus a clear identifiable patient group for the FDCs was missing. 3. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 4. There is also apparent lack of pharmacokinetic and pharmacodynamic compatibility - while levocetrizine is usually given once a day, phenylephrine or ambroxol would require more frequent administration. Use of Paracetamol in > one of the referred FDCs seems un- warranted, not to speak of the strength of the Paracetamol used (325 mg), which seems inadequate to treat fever or body-ache in adult subjects. 5. Safety & Efficacy: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 6. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 7. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2834	Dextromethorphan hydrobromide+bromhexine HCL+Guaiphenesin+menthol	5mg+4mg+100mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2836	Dextromethorphan hydrobromide+bromhexine HCL+Phenylephrine HCL+Menthol	5mg+4mg+5mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant. • Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. • Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2837	cetirizine HCL+phenylephrine HCL+Paracetamol +caffeine	5mg+5mg+500mg+30mg	Tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2845	Acrivastine+ Paracetamol IP+ Caffeine IP+ Phenylephrine HCl IP	8mg+325mg+25mg+5mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2846	Paracetamol IP+Phenylephrine HCl IP+Caffeine IP+Chlorpheniramine Maleate IP	500mg/500mg+10mg/10mg+32mg+2mg	Combikit (Film Coated Tablets)	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2847	Naphazoline HCl USP+C.M.C. IP+Menthol IP+Camphor IP+Phenylephrine HCl IP	0.056% + 0.5% + 0.005% + 0.01% + 0.012%	Drops	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2853	Dextromethorphan Hydrobromide IP+Cetirizine HCl IP	10mg+2.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2856	nimesulide + paracetamol + levocetirizine HCL+ phenylephrine HCL+ caffeine	100 mg+ 325 mg+ 2.5 mg + 5 mg+ 25 mg	tablet	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3. Nimesuilide- Safety concern	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2857	dextromethorphan HBr + phenylephrine HCL+ chlorpheniramine	10 mg+ 5 mg+ 2 mg	syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)

2864	bromhexine HCL+ dextromethophan HBr+ ammonium chloride	4 mg+ 5 mg + 50 mg+ 2.5 mg	syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2867	Terbutaline Sulphate+Ambroxo l HCl+Guaiphenesin +Zinc+Menthol	1.5mg+15m g+50mg+7. 5mg+0.5mg	Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2868	Paracetamol+Pheny lephrine HCl+Chlorphenira mine Maleate+Caffeine	325mg+5m g+2mg+30 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2869	Codeine Phosphate+Chlorph eniramine Maleate+AlcoholIP +Alcohol	10mg+4mg +0.15ml+3 %v/v	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2878	Dextromethorphan HCl+Phenylephrine HCl+Guaifenesin+ Triprolidine HCl	10mg+5mg +100mg+1. 25mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2888	Ammomium Chloride+Bromhexine HCl+Dextromethorphan HBR	50.0mg+4.0mg+5.0mg	Dekogest syrup	a, Pharmacodynamically irrelevant- 1. Bromhexine: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan decreases the cough impulse s expulsion of secretion would be hampered	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2889	Bromhexine HCl+Dextromethorphan Hydrobromide+Ammonium Chloride	4.0mg+5.0mg+50.0mg	Alvex cough syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2894	Bromhexine HCl+Ammonium Chloride+Dextromethorphan Hydrobromide	4.0mg+50.0mg+5.0mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2904	Paracetamol IP+Dextromethorphan Hydrobromide+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	170mg+5mg+2.5mg+1.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere wit the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2907	Chlorpheniramine Maleate IP+Sodium Citrate IP+Ammonium Chloride IP+Menthol IP	4mg+50mg+100mg+1mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2908	Diethylcarbamazine Citrate IP+Cetirizine HCL IP+Ambroxol HCL IP	150mg+5mg+30mg	Film Coated Tablets	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Ambroxol is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2909	Montelukast Sodium+Levocetirizine HCl IP+Acebrophylline	10mg+5mg+200mg	Film Coated Bilayered Tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2914	Ethylmorphine HCl IP+ Noscapine BP+ Chlorpheniramine Maleate IP	7.5mg+7.5mg+2.5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2917	Cetirizine HCl IP+Dextromethorphan Hydrobromide IP+Ambroxol HCl IP	5mg+15mg	Syrup	a, 1. Ambroxol: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan decreases the cough impulse so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Pharmacokinetic incompatibility amongst ingredients. 5.Use of anti-histamine with centrally acting anti-tussive ingredient is not rationale	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2918	Chlorepheniramine Maleate IP+Codeine Phosphate IP	4.00mg+10.00mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2919	Bromhexine HCl IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Paracetamol IP	8mg+5mg+2mg+100mg+325mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3.Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2920	Guaifenesin IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	100mg+10mg+5mg+2mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guaiphenesin:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 4. All ingredients have different therapeutic indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2921	Cetirizine Hcl IP+Phenylephrine HCl IP+Caffeine IP+Paracetamol IP	5mg+10mg+20mg+325mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2922	Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Menthol IP	8mg+10mg+100mg+5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2923	Promethazine HCl IP+Pholcodine IP	1.5mg+1.5 mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2925	Ambroxol HCl IP+ Guaifenesin IP+ Phenylephrine HCl IP+ Chlorpheniramine Maleate IP	15mg+50m g+5mg+2m g	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2927	Cetirizine HCl IP+Paracetamol IP+Phenylephirine HCl IP+Caffeine (anhydrous) IP	5mg+325m g+10mg+30 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2928	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaiphenesin IP+Ammonium Chloride IP	5mg+2.5mg +50mg+60 mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2932	Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Guaifenesin IP+Chlorpheniramine Maleate IP	10mg+4mg +50mg+2.5 mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2933	Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Phenylephrine Hydrochloride IP+Menthol IP	4mg+5mg+2.5mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2934	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Zinc Gluconate USP	125mg+2.5mg+1mg+5mg	Suspension	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2937	Paracetamol IP+Caffeine IP+Phenylephrine HCl IP	500mg+25mg+5mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2939	Dextromethorphan Hydrobromide IP+Bromhexine HCL IP+Phenylephrine HCl IP+Menthol IP	5mg+4mg+5mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2940	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP	5mg+2.5mg+50mg+60mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2943	Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Cetirizine HCl IP+Paracetamol IP+Caffeine Anhydrous IP	10mg+5mg +5mg+325 mg+30mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2949	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Bromhexine HCl IP	125mg+1.25mg+2.5mg +4.0mg	Oral Liquid	a, Pharmacodynamically irrelevant. • Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. • Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2954	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Bromhexine HCl IP	125mg+1.25mg+2.5mg +4.0mg	Oral Liquid	a, Pharmacodynamically irrelevant. • Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. • Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2958	Dextromethorphan Hydrobromide IP+Cetirizine HCl IP	10mg+2.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2959	Dextromethophan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP	5mg+2.5mg +50mg+60 mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2961	Dextromethorphan Hydrobromide IP+Bromhexine HCL IP+Ammonium Chloride IP+Menthol IP	5mg+4mg+50mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2965	Levocetirizine HCl IP+Dextromethorphan Hydrobromide IP+Zinc elemental	0.8mg+10.0mg+7.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2967	Dextromethorphan Hydrobromide IP+Cetirizine HCl IP	10mg+2.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2969	Paracetamol IP+Phenylephrine HCL IP+Levocetirizine IP+Caffeine IP	325mg+5mg+2.5mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2970	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	10mg+4mg+240mg+240mg+1.25mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2971	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP	5mg+2mg+50mg+75mg	Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2973	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Chloride IP	2.5mg+125mg+55mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2974	Dextromethorphan HBR IP+Guaiphenesin IP+Phenylephrine HCl IP+CPM	10mg+100mg+5mg+4mg	Syrup	a, I Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2978	Dextromethorphan Hydrobromide IP+Phenylephrine HCL IP+Paracetamol IP+Chlorpheniramine Maleate IP	5mg+5mg+250mg+2mg	Syrup	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2982	Paracetamol IP+Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Phenylephrine HCL IP+Diphenhydramine HCL IP	325mg+10mg+8mg+5mg+15mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug. 4.Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2986	Salbutamol Sulphate IP eq. to Salbutamol+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1mg+2mg+50mg+0.5mg	Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2988	Nimesulide IP+Paracetamol IP+Cetirizine HCl IP+Phenylephrine HCl IP+Caffeine anhydrous IP	100mg+325mg+5mg+5mg+30mg	Enteric Coated Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2990	Paracetamol IP+Phenylephrine HCl IP+Caffeine IP+Chlorpheniramine Maleate IP	325mg+5mg+16mg+2mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2996	Caffeine IP+Chlorpheniramine Maleate IP+Paracetamol IP+Phenylephrine HCl IP	30mg+2mg+500mg+5mg	Uncoated Tablets	This FDC was deceased earlier on 23.04.2014 by previous Committee and their comments are as under- The strength of Paracetamol in some cases appears inadequate to take care of headache, body ache or fever as claimed by the manufacturers in the indication. Necessary correction may be made in this regard. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 1. Safety & Efficacy. In all the FDC's as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 2. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 3. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months. As regard to Paracetamol IP 325mg +Phenylephrine HCl IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine anhydrous IP 30mg Tablets, firm claimed that the FDC is pre-1988 as per IMS Health data and they submitted a paper also in this regard. However adequate evidence shall be provided in this regard for this particular strength, failure of which will attract the above decision. The committee observed that there is a heterogeneity of caffeine dosages in these FDCs. Rationale for the same may be provided.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

2997	Chlorpheniramine Maleate BP+Codeine Phosphate BP	4mg+10mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2998	Codeine Phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
2999	Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Guaifenesin IP+Chlorpheniramine Maleate IP	10mg+8mg +100mg+2 mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3002	Paracetamol IP+Levocetirizine HCl IP+Phenylephrine HCl IP+Caffeine anhydrous IP	325mg+2.5 mg+10mg+ 15mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3003	Codeine Phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3004	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	5mg+125mg+56mg+1mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3005	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Noscapine IP+Sodium Citrate IP	2mg+28mg+7mg+3.25mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3006	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg+10mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3009	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg+10mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3010	Cetirizine Dihydrochloride IP+Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Guaifenesin IP	5mg+10mg+8mg+100mg	Uncoated Tablets	a, 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 3.Pharmacokinetic incompatibility amongst ingredients. 4.Use of anti-histamine with centrally acting anti-tussive ingredient is not rationale	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3011	Diethyl Carbamazine Citrate IP+Chlorpheniramine Maleate IP+Guaifenesin IP	150mg+4mg+100mg	Uncoated Tablets	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3013	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine IP	500mg+10mg/5mg+2mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2 Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3017	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP	5mg+2.5mg+50mg+60mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3019	Codeine Phosphate+Chlorpheniramine Maleate IP+	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3020	Bromhexine HCl+Guaifenesin IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	8mg+100mg+5mg+2mg+325mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Bromhexine :a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3025	Ambroxol HCl IP + Guaiphenesin IP+ Phenylephrine HCl IP + Chlorpheniramine Maleate IP + Menthol IP	15mg+ 50mg+ 2.5mg+ 2mg+1mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3027	Ketotifen Fumarate IP+Cetirizine Dihydrochloride IP	1mg+10mg	Uncoated Tablets	a, 1. No supporting published literature available on the combination. 2. Pharmakokinetic incompatibility,	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3030	Chlorpheniramine Maleate ip+Phenylephrine HCl IP+Paracetamol IP+Caffeine Anhydrous IP	2mg+5mg+ 325mg+30 mg	Uncoated Tablets	This FDC was discussed earlier on 23.04.2014 by previous Committee and their comments are as under- The strength of Paracetamol in some cases appears inadequate to take care of headache, body ache or fever as claimed by the manufacturers in the indication. Necessary correction may be made in this regard. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 1. Safety & Efficacy: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 2. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have urged in favor of better patient adherence and general acceptance by prescribers at large. 3. Therefore, in line, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommenced. The whole of the above exercise for protocol submission should be completed within 3 months. As regard to Paracetamol IP 325mg +Phenylephrine HCl IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine anhydrous IP 30mg Tablets, firm claimed that the FDC is pre-1988 as per IMS Health data and they submitted a paper also in this regard. However adequate evidence shall be provided in this regard for this particular strength, failure of which will attract the above decision. The committee observed that there is a heterogeneity of caffeine dosages in these FDCs. Rationale for the same may be provided.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3033	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Dextromethorphan Hydrobromide IP	250mg/170 ml+5.0mg/2.5mg+2.0mg/1.5mg+50.mg	Suspension	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3035	Terbutaline Sulphate IP+Bromhexine HCl IP+Etofylline BP	2.5mg+200 mg+8mg	Uncoated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3038	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP+Zinc Gluconate USP	125mg+2.5 mg+2.5mg+ 7.5mg	Syrup	a, 1.Pharmacodynamically and pharmacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3041	Paracetamol IP+Guaifenesin IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP	200mg+50 mg+2mg+2 mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3042	Paracetamol IP+Cetirizine HCL IP+Phenylephrine HCl IP+Caffeine IP	325mg+5m g+5mg+30 mg	Uncoated Tablets	a, 1.Pharmacodynamically and pharmacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3044	Ketotifen Fumarate IP+Theophylline (Anhydrous)	1mg+200m g	Tablets	a, Pharmacodynamically irrelevant- 1. Theophylline has narrow therapeutic index, and in FDC the toxicity of drug is major concern. 2. Pharmakokinetic incompatibility.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3045	Chlorpheniramine Maleate IP+Dextromethorphan Hydrobromide IP	4mg+10mg	Syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)
3046	Ambroxol HCl IP+Salbutamol Sulphate IP+Theophylline IP	30mg+2mg +100mg	Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3048	Bromhexine HCl IP+Dextromethorphan Maleate IP+Ammonium Chloride IP+Menthol IP	4mg+5mg+50mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3053	Paracetamol IP+Caffeine IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	325mg+5mg+5mg+25mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3054	Paracetamol IP+Caffeine IP+Phenylephrine HCl IP+Cetirizine HCl IP+Nimesulide BP	325mg+25mg+5mg+100mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3055	Cetirizine HCL IP+Nimesulide BP+Phenylephrine HCL IP	5mg+100mg+10mg	Uncoated Tablets	a, 1.Pharmacodynamically irrelevant as different ingredients have different therapeutic indication 2. Nimesulide: safety concern	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3060	Montelukast+Levocetirizine HCl+Acebrophylline SR	10mg+5mg+200mg	Tablets	a, Pharmacodynamically irrelevant- 1. There is no published literature supporting FDC of three drugs. 2. Pharmacokinetic imcompatibilty.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3062	Paracetamol+Phenylephrine+Caffeine	325mg+10mg+32mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3063	Levocetirizine HCl+Phenylephrine HCl+Ambroxol HCl+Paracetamol	5mg+5mg+30mg+325mg	Tablets	a, Pharmacodynamically irrelevant- 1.Multiple ingredient and diverse pharmacodynamic activity 2.Potential drug interaction. 3. Subtherapeutic dose of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3064	Paracetamol+Phenylephrine HCl+Chlorpheniramine Maleate+Caffeine	325mg+10mg+2mg+30mg	Uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3065	Cetrizine HCl+Paracetamol+Phenylephrine+Zinc Gluconate	2.5mg+125mg+5mg+7.5mg	Syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3067	Paracetamol+Phenylephrine+Cetrizine+Zinc Gluconate	325mg+5mg+5mg+7.5mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

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3068	CPM+Phenylephrine+Paracetamol+Zinc Gluconate	1mg+2.5mg+325mg+7.5mg	Tablets	a, 1.Pharmacodynamically and pharmacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3070	Paracetamol+Chloropheniramine maleate+Phenylephrine+Dextromethorphan Hydrobromide+Caffeine	650mg+4mg+10mg+15mg+30mg	Sachet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3072	Chlorpheniramine maleate+Dextromethorphan HBr+Paracetamol+Phenylephrine HCl	2mg+10mg+250mg+5mg	Suspension	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3076	Paracetamol+Levocetirizine HCl+Phenylephrine HCl+Ambroxol HCl	325mg+2.5mg+5mg+60mg	Film Coated Tablets	This FDC was deceased earlier on 23.04.2014 by previous Committee and their comments are as under- The committee carefully examined the composition of each FDC, their indications as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observes the following: 1. The products of agenda 1 and 2 combines expectorants and cough suppressants. Thus the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient. 2. The products of agenda 3 and 4 contain actives like levocetrizine (anti-histamine), phenylephrine (decongestant), ambroxol (mucolytic-expectorant) and paracetamol; the indications are dry cough, allergic rhinitis, body ache and fever, upper respiratory affections etc. The medical rationale for combining these actives is inadequate and the FDC's tend to accommodate diverse types of patient situations and symptoms which usually do not co-exist. Thus a clear identifiable patient group for the FDC's was missing. 3. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 4. There is also apparent lack of pharmacokinetic and pharmacodynamic compatibility - while levocetrizine is usually given once a day, phenylephrine or ambroxol would require more frequent administration. Use of Paracetamol in some of the referred FDC's seems un- warranted, not to speak of the strength of the Paracetamol used (325 mg), which seems inadequate to treat fever or body-ache in adult subjects. 5. Safety & Efficacy: In all the FDC's as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 6. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 7. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3077	Paracetamol+Phenylephrine HCl+Caffeine+Chlorpheniramine Maleate	325mg+10mg+30mg+2mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3078	Acetaminophen+Guaifenesin+Dextromethorphan Hydrobromide+Chlorpheniramine Maleate	125mg+25mg+7.5mg+5mg+1mg	Syrup	a, 1. Use of anti-histamine with centrally acting anti-tussive ingredient is not rationale 2. Patients may need only one ingredient and use of FDC may lead to misuse. 3.Different mechanism of action without synergistic action. 4.Also the Acetaminophen, an antipyretic, is not indicated in the cough syrup. (04.01.2016)	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3081	Chlorpheniramine maleate+Dextromethorphan HBr+Paracetamol+Phenylephrine HCl	2mg+10mg+250mg+5mg	Suspension	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3082	Paracetamol+Bromhexine HCl+Guaiphenesin+Chlorpheniramine Maleate+Phenylephrine HCl	325mg+8mg+50mg+2mg+5mg	Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3086	Cetirizine Dihydrochloride+Dextromethorphan Hydrobromide+Phenylephrine HCl+Tulsi	5mg+10mg+5mg + 0.1%v/v	Syrup	a, 1.Pharmacodynamically and pharmacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Use of anti-histamine with centrally acting anti-tussive ingredient is not rationale	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3087	Cetirizine HCl+Dextromethorpham Hydrobromide+Ambroxol HCl	5mg+10mg+15mg	Oral Liquid	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3088	Terbutaline Sulphate+Bromhexine HCl+Etofylline	2.5mg+100mg+8mg	Uncoated tablet	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drug is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3089	Dextromethrpahn Hydrobromide+Cetirizine Dihydrochloride+Phenylephrine HCl+Menthol	10mg+5mg+5mg+1.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3092	Ceterizine HCl+Phenylephrine HCl+Paracetamol+Ambroxol HCl+Caffeine anhydrous	5mg+10mg+325mg+30mg+20mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3093	Guaifenesin+Dextromethorphan Hydrobromide	100mg+10mg	5ml syrup	a, Pharmacodynamically irrelevant- 1. Guaiphenesin :a mucolytic which increases mucus secretion. 2. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered (04.01.2016)	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3094	Paracetamol+Phenylephrine HCl+Caffeine+Chlorpheniramine Maleate	500mg+10mg+30mg+2mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3096	Paracetamol+Bromhexine HCl+Chlorpheniramine maleate+Guaiphenesin+Phenylephrine HCl	325n.g+8mg+2mg+100mg+5mg	Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3098	Levocetirizine Dihydrochloride IP+Paracetamol IP+Phenylephirine HCl IP+Caffeine Anhydrous IP	2.5mg+325mg+10mg+30mg	Film Coated Tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3099	Dextromethorphan Hydrobromide IP+Paracetamol IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP	10mg+250mg+5mg+2mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3102	Paracetamol IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP	125mg+5mg+2.5mg+1mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3103	Paracetamol IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP	250mg+10mg+5mg+2mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3105	Paracetamol IP+Phenylephrine HCl+Chlorpheniramine Maleate IP+Caffeine (Anhydrous)	325mg+5mg+2mg+15mg	Uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3106	Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Bromhexine HCl IP+Menthol IP	5mg+50mg+2mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3108	Caffeine (Anhydrous) IP+Paracetamol IP+Phenylephrine HCl IP+ Chlorpheniramine Maleate IP	30mg+35mg+2.5mg+2mg	Uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3109	Paracetamol (Acetaminophen) IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	170mg+5mg+2.5mg+1.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3111	Ketotifen Fumarate IP+Levocetrizine Dihydrochloride IP	1mg+5mg	Film Coated Tablets	a, 1. No supporting published literature available on the combination. 2. Pharmakokinetic incompatibility.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3112	Paracetamol IP+Levocetirizine HCl IP+Phenylephirine HCl IP+Zinc Gluconate USP	325mg+2.5 mg+10mg+ 7.5mg	Film Coated tablets	a, 1. Paracetamol dose is subtherapeutic. 2. Pharmacokinetic incompatibility. 3. Potential for drug-drug interaction. 4. No published literature supporting addition of Zinc in this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3114	Paracetamol IP+Phenylephrine HCl IP+Triprolidine HCl IP+Caffeine IP	500mg+5m g+1.25mg+ 15mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3115	Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Paracetamol IP+Cetirizine HCl IP	5mg+5mg+ 125mg+2m g	Syrup	a, Pharmacodynamically irrelevant-1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3119	Dextromethorphan Hydrobromide IP+Guaiphenesin IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP	10mg+100 mg+8mg+2 mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3120	Caffeine (Anhydrous) IP+Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	30mg+325 mg+10mg+ 5mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3121	Dextromethorphan Hydrobromide IP+Phenylephirine HCl IP+Guaifenesin IP	10mg+4mg +5mg+100 mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3123	Bromhexine HCl IP+Ammonium Chloride IP+Dextromethorp han Hydrobromide IP	4mg+50mg +5mg	Syrup	a, 1.Pharmacologically no synergistic effect 2. Multiple ingredients with diverse pharmacologica profile susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3125	Paracetamol IP+Caffeine IP+Phenylephrine HCl+Chlorpheniramine Maleate IP	500mg+30 mg+10mg+ 4mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3127	Dextromethorphan Hydrobromide IP+Triprolidine HCl IP+Phenylephrine HCL	10mg+1.25 mg+5mg	Syrup	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3129	Guaiphenesin IP+Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	100mg+10mg+5mg+4mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3133	Ambroxol HCl IP+ Levocetirizine HCl IP+ Phenylephrine HCl IP+ Guaiphenesin IP+ Menthol IP	15mg+0.8mg+5mg+50mg	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may no need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3135	Levocetirizine HCl IP+Paracetamol IP+Phenylephrine HCl IP+Caffeine IP	5mg+325mg+5mg+30mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3138	Chlorpheniramne Maleate IP+Ammonium Chloride +Sodium Citrate	2.5mg+125mg+55mg per 5ml	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3143	Pseudoephedrine HCl IP+Cetirizine HCl IP	60mg+5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1.Both increase the sedation as adverse effect. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3146	Dextromethorphan Hydrobromide IP+Guaifenesin IP+Bromhexine HCl IP+Chlorphenirami ne Maleate IP	10mg+100 mg+8mg+2 mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3147	Dextromethorphan Hydrobromide IP+Chlorphenirami ne Maleate IP+Ammonium Chloride IP+Menthol IP	5mg+2mg+ 50mg+2.5m g	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3151	Cetirizine HCl IP+Paracetamol IP+Caffeine IP+Phenylephirine HCl IP	5mg+325m g+30mg+5 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3154	Ambroxol HCl IP+Guaiphenesin IP+Chlorphenirami ne Maleate IP+Phenylephirine HCl IP+Menthol IP	15mg+50m g+2mg+2.5 mg+1mg	Liquids	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3155	Nimesulide BP+Paracetamol IP+Cetirizine HCl IP+Phenylephrine HCl IP+Caffeine IP	100mg+325 mg/500mg+ 5mg+5mg+ 30mg	Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs *Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3157	Levocetirizine Dihydrochloride IP+Paracetamol IP+Phenylephrine HCl IP+Caffeine Anhydrous IP	2.5mg+500 mg+10mg+ 30mg	Uncoated Tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3158	Paracetamol IP+Caffeine Anhydrous IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	325mg+25 mg+5mg+2 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3161	Salbutamol Sulphate IP eq. to Salbutamol+Aminophylline IP+Guaifenesin IP	2mg+105mg+100mg	Oral Liquid	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3163	Salbutamol Sulphate IP eq. to Salbutamol +Thoephylline IP+Bromhexine HCl IP	2mg+100mg+8mg	Uncoated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3165	Dextromethorphan Hydrobromide IP+Guaiphenesin IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP	10mg+100mg+8mg+2mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3166	Paracetamol IP+Guaiphenesin IP+Ambroxol HCl IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	325mg+100mg+30mg+10mg+2mg	Film Coated tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3167	Codeine Phosphate+Chlorpheniramine Maleate IP	10mg+4mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3169	Nimesulide BP+Paracetamol IP+Cetirizine HCl IP+Phenylephirine HCl IP+Caffeine IP	100mg+325 mg+5mg+1 0mg+25mg	Film Coated Tablets	a, 1. Nimesulide in combination has potential of misus in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility amon the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3171	Ambroxol HCl IP+Chlorpheniramine Maleate IP+Guaiphenesin IP+Phenylephrine HCl IP+Menthol IP	15mg+2mg +50mg+5m g+1mg	Oral Liquid	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3172	Chlorpheniramine maleate IP+Dextromethorp han Hydrobromide IP+Guaifenesin IP+Phenylephrine HCl IP	4mg+5mg+ 100mg+5m g	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3173	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine anhydrous IP	325mg+5m g+2mg+30 mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3178	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine anhydrous IP	325mg+5mg+2mg+30mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3179	Dextromethorphan Hydrobromide IP+Cetirizine HCl IP+Ambroxol HCl	10mg+5mg+15mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3181	Paracetamol IP+Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP	125mg+5mg+2mg+5mg per 5ml	Oral Suspension	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3186	Chlorpheniramine Maleate IP+Dextromethorphan Hydrobromide IP+Paracetamol IP+Phenylephrine HCl IP	2mg+15mg+325mg+5mg	Film Coated Tablets	a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3193	Paracetamol+Phenylepherine HCl+Chlorpheniramine Maleate+Caffeine	500mg+5mg+2mg+30mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3194	Dextromethorphan HBr+Bromohexine HCl+Chlorpheniramine maleate+Guaiphensin	10mg+8mg+2mg+100mg	Uncoated tablet	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3195	Codeine Phosphate+Chlorpheniramine maleate	10mg+4mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3196	Caffeine anhydrous+ Paracetamol+ Chlorpheniramine maleate	25mg+325mg+2mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3199	Dextromethorphan Hydrobromide+ Sodium Citrate+ Chlorpheniramine maleate	7.5mg+130mg+2.5mg	Syrup	a,	C Inadvertatntly included as "a". Same is approved by DCG(I)
3200	Paracetamol+Phenylephrine HCl+Dextromethorphan Hydrobromide+chlorpheniramine maleate	325mg+10mg+15mg2.0mg	Uncoated tablet	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3201	Dextromethorphan Hydrobromide+ Guaiphenesin+ Phenylephrine HCl+ Chlorpheniramine maleate	10mg+100mg+5.0mg+4.0mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3203	Ammonium Chloride+Dextromethophan+Cetirizine HCl+Menthol	50mg+5mg+2.5mg+2.5mg	Syrup	a, 1. Pharmacodynamically irrelevant. 2. Pharmacokinetic incompatiblity amongst the ingredients 3.Use of anti-histamine with centrally acting anti-tussive ingredient is not rationale	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3204	Paracetamol+Phenylephrine HCl+Levocetirizine HCl+Caffeine anhydrous	500mg+10mg+2.5mg+30mg	Uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3207	Dextromethorphan HBr+Paracetamol+Cetirizine HCl+Phenylephrine HCl	10mg+325mg/500mg+5mg+5mg	Uncoated tablet	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3210	Chlorpheniramine maleate+Terpin Hydrate+Antimony Potassium Tartrate+Ammonium chloride+Sodium Citrate+Menthol	4mg+8mg+0.6mg+100mg+100mg+1mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3221	Bromhexine HCl+Dextromethorphan Hydrobromide+Ammonium Choride+Menthol	8mg+10mg+100mg	Oral liquid	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3222	Codeine Phosphate+Chlorpheniramine maleate	10mg+4mg	Oral liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3224	Paracetamol+Bromhexine HCl+Chlorpheniramine maleate+Phenylephrine HCl+Guaiphenesin	325mg+8mg+2mg+5mg+100mg	Film Coated Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3225	Promethazine HCl+Pholcodine	1.5mg+1.5mg	Oral liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3226	Terbutaline Sulphate+Etofylline+Ambroxol HCl	2.50mg+100mg+30mg	Uncoated tablet	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3227	Dextromethorphan Hydrobromide+Bromhexine HCl+Ammonium Chloride+Menthol	5.0mg+4.0mg+50mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant. • Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. • Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered • Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3232	Phenylephrine HCl IP+Bromhexine Hydrobromide IP+Guaiphenesin IP+Chlorpheniramine Maleate IP+Paracetamol IP	5mg+8mg+100mg+2mg+325mg	Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3233	Paracetamol IP+Phenylephrine HCl IP+Cetirizine Dihydrochloride IP+Caffeine anhydrous IP	325mg+10mg+5mg+30mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3234	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine anhydrous IP	325mg+10mg+2mg+30mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3237	Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Cetirizine HCl IP+Menthol IP	10mg+5mg+5mg+1.5mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3238	Nimesulide BP+Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP+Caffeine IP	100mg+325 mg+5mg+5 mg+30mg	Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi-ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesuilide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3244	Dextromethophan Hydrobromide IP+Bromhexine HCl IP+Ammonium Chloride IP	5mg+4mg+ 50mg	Liquids	a, Pharmacodynamically irrelevant-, • Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered • Ammonium Chloride: increase the mucus secretion in respiratory tract • Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3247	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Dextromethorphan Hydrobromide IP	250mg/250 mg+2mg/2 mg+2.5mg/ 5mg+5mg/5 mg	Liquids	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3248	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Caffeine IP	325mg/500 mg+2mg+5 mg+30mg	Uncoated tablet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3251	Phenylephrine HCl IP+Paracetamol IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP	2.5mg+125 mg+2.0mg+ 1mg	Liquids	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3252	Cetirizine HCl IP+ Phenylephirine HCl IP+ Paracetamol IP+ Caffeine anhydrous IP	5mg+5mg+ 325mg+30 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3257	Promethazine HCl+Pholcodine+Phenylephrine HCl	1.5mg+1.5 mg+2.5mg	Oral liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3267	Phenylephrine HCl IP+Paracetamol IP+Caffeine IP+Chlorpheniramine Maleate IP	5mg+325mg+15mg+2 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3268	Dextromethorphan Hydrobromide IP+Tripolidine HCl IP+Phenylephirine HCl IP	10mg+1.25 mg+5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3273	Triprolidine HCl IP+Phenylephrine IP+Paracetamol IP	0.625mg+5 mg+125mg	Syrup	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3277	Bromhexine HCl IP+Dextromethorp han Hydrobromide IP+Ammonium Chloride IP+Menthol IP	8mg+10mg +100mg+5 mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3278	Paracetamol IP+Caffeine Anhydrous IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	325mg+30 mg+10mg+ 2mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3279	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	2.5mg+125 mg+55mg+ 1mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3282	Paracetamol IP+Caffeine Anhydrous IP+Chlorpheniramine Maleate IP	320mg+20 mg+4mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Paracetamol dose is subtherapeutic. 2. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3283	Guaifenesin IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Chlorpheniramine Maleate IP	50mg+5mg+60mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guaiphenesin:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3. Ammonium Chloride: increase the mucus secretion in respiratory tract 4. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 5. All ingredients have different therapeutic indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3288	Phenylephrine HCl IP+Paracetamol IP+Caffeine IP+Chlorpheniramine Maleate IP	5mg+325mg+15mg+2mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3289	Paracetamol IP+Caffeine (Anhydrous) IP+Phenylephrine HCl IP+CetirizineDihydrochloride IP	325mg+30mg+10mg+5mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3290	Paracetamol IP+Codeine Phosphate IP+Chlorpheniramine Maleate IP	325mg+10mg+2mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Paracetamol dose is subtherapeutic. 4.There is also a risk of abuse potential.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3292	Codeine Phosphate IP+Chlorphenirami ne Maleate IP	10mg+4mg	Liquid Oral	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3296	Dextromethorphan Hydrobromide IP+Chlorphenirami ne Maleate IP+Guaiphenesin IP+Ammonium Chloride IP	5mg+2.5mg +50mg+60 mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3299	Paracetamol IP+Pseudoephedrin e HCl IP+Cetirizine HCl IP+Caffeine (Anhydrous) IP	500mg+60 mg+5mg+3 0mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Caffeine is CNS stimulant where as Pseudoephedrine leads to sedation. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3302	Ambroxol HCl IP+Guaiphenesin IP+Phenylephrine HCL IP+Chlorphenirami ne Maleate IP	15mg+50m g+5mg+2m g	Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3304	Paracetamol IP+Phenylephrine HCl IP+Chlorphenirami ne Maleate IP+Caffeine IP	500mg+5m g+2mg+30 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3305	Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Chlorphenirami ne Maleate IP+Guaifenesin IP	5mg+60mg +2.5mg+50 mg	Liquid Oral	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3307	Ambroxol Hcl IP+ Guaifenesin IP+ Chlorpheniramine Maleate IP+ Phenylephrine HCl IP	15mg+50m g+2mg+5m g	Liquid Oral	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3309	Paracetamol IP+Ambroxol HCl IP+Phenylephrine HCl IP+Chlorphenirami ne Maleate IP	125mg+15 mg+5mg+2 mg	Syrup	a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3310	Codeine Phosphate IP+Chlorphenirami ne Maleate IP	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3312	Paracetamol IP+Phenylephrine HCl IP+Desloratadine+ Zinc Gluconate USP+Ambroxol HCL IP	250mg+5m g+1.25mg+ 10mg+15m g	Oral Liquid	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3313	Paracetamol IP+Phenylephrine HCl IP+Desloratadine+ Zinc Gluconate USP+Amoroxol HCl IP	125mg+2.5 mg+0.5mg+ 5mg+7.5mg	Oral Liquid	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3323	Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Ammonium Chloride IP	5mg+ 4mg+ 50mg	Liquid Oral	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up them were thoroughly secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3327	Phenylephrine HCl+Paracetamol IP+Caffeine Anhydrous+Chlorpheniramine Maleate	5mg+500mg+30mg+2.0mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3329	Paracetamol IP+Phenylephrine HCl IP+Caffeine (anhydrous) IP	500 mg + 10 mg + 32 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3330	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	2.5mg+125 mg+55mg+ 0.5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3333	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Menthol IP	2.5mg+125 mg+1.25mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3334	N-Acetyl Cysteine USP+ Ambroxol Hydrochloride IP+ Phenylephrine Hydrochloride IP+ LevocetirizineHydrochloride IP	200mg + 30mg +2.5mg +2.5mg	Film Coated Tablet	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3. Potential for Drug-Drug interaction. 4. Indication of N-acetyl cystine in the FDC is irrelevant.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3341	Dextromethorphan Hydrobromide IP+Phenylephrine Hcl IP+Tripolidine Hcl IP+Menthol IP	10.0mg+2.5 mg+1.25mg +1.50mg	Syrup	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3345	Dextromethorphan Hydrobromide IP+AmmoniumChloride IP+Bromhexine Hydrochloride IP+Menthol IP	5mg+50mg +2mg+2.5mg	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3350	Chlorpheniramine maleate Ip+Codeine Phosphate ip	4mg+10mg	Liquid Oral	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3351	Paracetamol IP+Phenylephrine HydrochlorideIP+Cetirizine Hydrochloride IP+Caffeine Anhydrous IP	325mg+10mg+5mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3353	Bromhexine Hydrochloride IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP+Menthol IP	4mg+5mg+50mg+2.5mg	Liquid Orals	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3354	Paracetamol IP+Chlorpheniramine Maleate IP+Caffeine(Anhydrous) IP	300mg+4mg+15mg	Expectorent (uncoated tablet)	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Paracetamol dose is subtherapeutic. 4.Dosing shedule of the ingredients is incompatible. 5. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3355	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg+10mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3357	Paracetamol IP+Phenylephrine Hydrochloride IP+Cetirizine Hydrochloride IP+Caffeine (anhydrous) IP	650mg/500mg+5mg/5mg+5mg/5mg+30mg/30mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3358	Salbutamol Sulphate IP eq. to Salbutamol+Cetirizine Hydrochloride IP+Ambroxol Hydrochloride IP	2mg+5mg+30mg	Film Coated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drug is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3360	Paracetamol IP+Phenylephrine Hydrochloride IP+Levocetirizine Hydrochloride IP+Caffeine (anhydrous) IP	500mg+5mg+5mg+30mg	Film Coated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3363	Dextromethorphan Hydrobromide IP+Phenylephrine Hydrochloride IP+Bromhexine Hydrochloride IP+Guaifenesin IP9 Chlorpheniramine Maleate IP	10mg+5mg+8mg+50mg+2mg	Uncoated Tablet	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3364	Paracetamol IP+Phenylephirine Hydrochloride IP+Chlorpheniramine Maleate IP+Caffeine (anhydrous) IP	500mg+10mg+2mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3367	Dextromethorphan Hydrobromide IP+Triprolidine Hydrochloride IP+Phenylephrine Hydrochloride IP	10mg+1.25mg+5mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3368	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP	10mg+4mg	Syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)

3379	Paracetamol IP+Bromhexine HCl IP+Chlorpheniramine maleate ip+Guaiphenesin IP	300mg+8mg+2mg+50mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. • Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. • Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3381	Salbutamol Sulphate IP eq. to Salbutamol+Theophylline Anhydrous IP+Bromhexine HCl IP	2mg+100mg+8mg	Uncoated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3382	Paracetamol IP+Levocetirizine Hcl IP+Phenylephrine Hcl IP+Ambroxol Hcl IP	325mg+5mg+5mg+30mg	Uncoated Tablets	This FDC was deceased earlier on 23.04.2014 by previous Committee and their comments are as under- The committee carefully examined the composition of each FDC, their indications as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observes the following: 1. The products of agenda 1 and 2 combines expectorants and cough suppressants. Thus the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient. 2. The products of agenda 3 and 4 contain actives like levocetirizine (anti-histamine), phenylephrine (decongestant), ambroxol (mucolytic-expectorant) and paracetamol; the indications are dry cough, allergic rhinitis, body ache and fever, upper respiratory infections etc. The medical rationale for combining these actives is inadequate and the FDC's tend to accommodate diverse types of patient situations and symptoms which usually do not co-exist. Thus a clear identifiable patient group for the FDCs was missing. 3. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 4. There is also apparent lack of pharmacokinetic and pharmacodynamic compatibility - while levocetrizine is usually given once a day, phenylephrine or ambroxol would require more frequent administration. Use of Paracetamol in some of the referred FDC's seems un- warranted, not to speak of the strength of the Paracetamol used (325 mg), which seems inadequate to treat fever or body-ache in adult subjects. 5. Safety & Efficacy: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 6. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 7. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3383	Nimesulide BP+Cetirizine Hcl IP+Phenylephrine Hcl IP	100mg+5mg+5mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Potential for nimesulide toxicity and misuse in FDC. 4.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3384	Dextromethorphan Hydrobromide IP+bromhexine Hcl IP+Chlorphenirami ne Maleate IP+Guaiphenesin IP	10mg+8mg +2mg+100 mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3385	Naphazoline Hcl USP+Chlorpheniramine Maleate IP+Zinc Sulphate IP+Boric Acid Ip+Sodium chloride IP+chlorobutol IP (As Preservative)	0.056% w/v + 0.01% w/v + 0.12% w/v + 1.25% w/v + 0.05% w/v + 0.035% w/v	Eye Drops	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3386	Paracetamol IP+Phenylephrine Hcl IP+Chlorphenirami ne Maleate IP+Caffeine (anhydrous) IP	325mg+10 mg+2mg+3 0mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3387	ParacetamolIP+Bro mhexine HclIP+Phenylephri ne Hcl IP+Chlorphenirami ne Maleate IP+Guaifenesin IP	325mg+4m g+5mg+4m g+50mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible. 3. Paracetamol dose is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3388	ParacetamolIP+Lev ocetirizine Hcl IP+Caffeine (anhydrous) IP+Phenylephrine Hcl IP	500mg+2.5 mg+30mg+ 10mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3389	Salbutamol Sulphate IP eq. to Salbutamol+Bromhexine HydrochlorideIP	2mg+8mg	Uncoated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3390	ParacetamolIP+Phenylephrine Hcl IP+Chlorpheniramine Maleate IP+Caffeine (anhydrous) IP	325mg+5mg+2mg+15mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3391	Dextromethorphan Hydrobromide IP+Phenylephrine Hcl IP+Guaifenesin IP+Cetirizine Hcl IP+Acetaminophen IP	10mg+5mg+50mg+5mg+325mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3392	Guaifenesin+ Bromhexine HCL+ Chlorpheniramine HCL+ Paracetamol	100 mg+ 8 mg+ 5 mg+ 2 mg	tablet	a, Pharmacodynamically irrelevant- 1. Guaiphenesina mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. paracetamol : addition of paracetamol express the consumers to the hepatotoxic effect of antipyretic unnecessarily 3. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 4.All ingredients present in the FDC have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3395	Paracetamol IP+Phenylephrine HCl Chlorpheniramine Maleate IP+Caffeine IP(Anhydrous)	500mg+10mg+2mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3399	Phenylephrine HCl+Chlorpheniramine Maleate+Caffiene+Paracetamol	5mg+2mg+16mg+500mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3403	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Chloroform IP+Menthol IP	3mg+110mg+18.5mg+0.9mg	Solution	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3404	Betholite-PD (Salbutamol Sulphate IP+Choline Theophylinate BP+Ambroxol HCl IP	1mg+50mg+15mg	Oral Liquid	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3405	Guaiphenesin IP+Dextromethophan Hydrobromide+Chlorpheniramine Maleate IP+Phenylephirine HCl IP	10mg+10mg+4mg+5mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered . 3.Patients may need only one ingredient and use of FDC may lead to misuse. 4.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3406	Salbutamol Sulphate IP eq. to salbutamol IP+Choline Theophylinate BP+Ambroxol HCl BP	1mg+50mg+15mg	Oral Liquid	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3409	Chlorpheniramine Maleate + Codeine Phosphate IP	4mg+10mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3410	Dextromethorphan Hydrobromide+Guaifenesin+Chlorpheniramine Maleate+Phenylephrine Hcl	10mg+4mg +100mg+5 mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes.. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3411	Codeine Phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3415	Codeine Phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3420	Chlorpheniramine Maleate IP+Codeine Phosphate IP+Menthol IP	4mg+10mg +0.1mg	Nil	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3424	Dextromethorphan Hydrobromide+Guaifenesin+Chlorpheniramine Maleate+Ammonium Chloride IP	5mg+50mg+2.5mg+60mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3432	Dextromethorphan Hydrobromide+Cetirizine HCl IP+Phenylephirine Hcl IP+Menthol IP	10mg+5mg+5mg+1.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3433	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	5mg+100mg+40mg+1mg	Syrup	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3439	Chloropheniramine Maleate IP+Phenylephrine HCl IP+Dextromethorphan Hydrobromide IP	2mg+5mg+10mg	Syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)
3443	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	3mg+130mg+65mg+0.5mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3445	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg+10mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3448	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	3mg+130mg+65mg+0.5mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3449	Diphenyhydramine HCl IP+Terpine Hydrate USP+Ammonium Chloride IP+Sodium Citrate IP	12.5mg+7.5mg+125mg+55mg+1.5mg	Oral Liquid	a, Pharmacodynamically irrelevant. No published literature supporting the combination	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3451	Chlorpheniramine Maleate IP+Codeine Phosphate IP	4mg+10mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3452	Pseudoephedrine HCl IP+Bromhexine HCl IP	60mg+8mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1.Mucokinetic increases mucus secretion and decongestant will dry up secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3453	Cetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP+Caffeine (Anhydrous) IP+Nimesulide BP	5mg+10mg +325mg+25 mg+100mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3455	Dextromethorphan Hydrobromide IP+Bromhexine HCl IP+Ammonium Chloride IP+Menthol IP	5mg+4mg+ 50mg+50m g	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3456	Guaifenesin IP+Dextromethorp han Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	100mg+10 mg+5mg+4 mg	Syrup	a, Pharmacodynamically irrelevant- 1. Guaiphenesin:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2, Dextromethorphan: it decreases the cough impuls so expulsion of secretion would be hampered 3. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 4. All ingredients have different therapeutic indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3459	Dextromethorphan Hydrobromide+Lev ocetirizine HCl IP+Phenylephrine HCl IP+Zinc Gluconate eq. to elemental Zinc	10mg+2.5m g+5mg+7.5 mg	Expector ent	1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere wit the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3463	Dextromethorphan Hidrobromide IP+Cetirizine Di HCl IP+Guaifenesin IP+Ammonium Chloride IP	10ml+5mg+ 50mg+60m g	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere wit the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3468	Levocetirizine+Paracetamol+Phenylephrine+Caffeine	5mg+325mg+5mg+25mg	Uncoated Tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3. Subtherapeutic dose of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3472	Levocetirizine Hcl IP+Ambroxol HCl IP+Guaifenesin IP+Phenylephirine HCl IP+Menthol IP	0.8mg+15mg+50mg+5mg	Oral Suspension	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3473	Paracetamol IP+Phenylephrine HCl IP+Levocetirizine HCl IP+Sodium Citrate IP	250mg+5mg+1.25mg+60mg	Oral Suspension	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3476	Ambroxol HCl IP+Salbutamol Sulphate IP eq. to Salbutamol+Choline Theophyllinate BP+Menthol IP	15mg+1mg+55mg+1mg	Oral Liquid Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drug is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3489	Paracetamol IP+Chlorpheniramine maleate IP+Caffeine Anhydrous IP	325mg+2mg+25mg	Uncoated tables	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Paracetamol dose is subtherapeutic. 4.Dosing shedule of the ingredients is incompatible. 5. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3504	Paracetamol IP+Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate IP+Caffeine IP	500mg+10mg+2mg+25mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submicted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3506	Paracetamol IP+Chlorpheniramine Maleate IP+Ambroxol Hydrochloride IP+Guaifenesin IP+Phenylephrine Hydrochloride IP	500mg+2mg+30mg+100mg+10mg	Film Coated Tablets	a, Pharmacodynamically irrelevant. • Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry u secretions. • Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3507	Levocetirizine Hydrochloride IP+Phenylephrine Hydrochloride IP+Ambroxol Hydrochloride IP+Guaiphenesin IP+Paracetamol IP	2.5mg+10mg+60mg+100mg+325mg	Uncoated tablets	a, 1. Pharmacodynamically irrelevant-Patients may no need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule. 3.Potential drug interation. 4. Subtherapeutic dose of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3509	Levocetirizine Hydrochloride IP+Paracetamol IP+Phenylephrine Hydrochloride IP+Caffeine anhydrous eq. to caffeine	2.5mg+500mg+10mg+30mg	Uncoated tablets	a, 1. Pharmacodynamically irrelevant-Patients may no need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3511	Chlorpheniramine Maleate IP+Codeine Phosphate IP+Menthol IP	4mg+10mg+0.1mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3512	Chlorpheniramine Maleate IP+Vasaka Extract eq. to Vasaka IP '66+Tolubalsm IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	4mg+133mg+6.25mg+100mg+60mg+1mg	Oral Liquid	a, Pharmacodynamically irrelevant- 1. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 2. Ammonium Chloride: increase the mucus secretion in respiratory tract.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3513	Bromhexine Hcl IP+Cetrizine Hcl IP+Phenylephrine HCl IP+Guaifenesin IP+Menthol IP	4mg+2.5mg+5mg+50mg+1mg	Oral Liquid	a, 1.Pharmacologically no synergistic effect 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility. 3. Pharmacokinetically incompatibiliy.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3514	Dextromethorphan Hydrobromide IP+Ambroxol Hcl IP+Ammonium Chloride IP+Chlorpheniramine Maleate IP+Menthol IP	5mg+15mg+50mg+2mg+2.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3515	Ambroxol Hcl IP+Chlorpheniramine Maleate IP+Phenylephrine Hcl IP+Guaifenesin IP+Menthol IP	15mg+2mg+5mg+50mg+1mg	Oral Liquid-Syrup	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3518	Dextromethorphan Hydrobromide IP+Phenylephrine Hcl IP+Cetirizine HCl IP+Zinc Gluconate USP as elemental Zinc+Menthol IP	10mg+5mg+5mg+7.5mg+1.5mg	Oral Liquid-Syrup	a, Pharmacodynamically irrelevant- 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3520	Diethylcarbamazine Citrate IP+Guaiphenesin IP+Chlorphenirami ne Maleate	100mg+60 mg+2mg	Film Coated Tablets	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3521	Diethylcarbamazine Citrate IP+Guaiphenesin IP+Chlorpnenirami ne Maleate	50mg+50m g+1mg	Film Coated Tablets	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3522	Diethylcarbamazine Citrate IP+Guaifenesin IP+Chlorphenirami ne Maleate	250mg+150 mg+4mg	Film Coated Tablets	a, Pharmacodynamic irrelevant - 1. Patient may need only one ingredient and use of FDC may lead to misuse. 2.Guaiphenesin is not indicated for eosinophillia, as it is a mucolytic which increases mucus secretion and should not be given in combination with antihistaminic with anti cholinergic properties.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3523	Terbutaline Sulphate IP+ N-Acetyl L-Cysteine USP+ Guaifenesin IP	2.5mg+200 mg+100mg	Sachets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3524	Calcium Gluconate IP+Levocetirizine Dihydrochloride IP	500mg+5m g	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1.Each ingredients have different indication. 2.This combination does not follow the concept and purpose of FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3528	Paracetamol IP+Levocetirizine Di hydrochloride IP+Pseudoephedrine Hcl IP	650mg+2.5mg+60mg	Film Coated Tablets	a, 1. Paracetamol dose high 2. Pharmacokinetic incompatibility. 3. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3536	Dextromethorphan Hydrobromide IP+Chlorpheeniramine Maleate IP+Guaifenesin IP+Ammonium Chloride IP	5mg+2.5mg+50mg+60mg	Liquid Orals	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3548	Chloropheniramine maleate IP+Codeine Phosphate IP	4mg+10mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3550	Dextromethorphan Hydrobromide IP+Cetirizine Hcl IP+Phenylephrine HCl IP+Menthol IP	10mg+5mg+5mg+1.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3553	Salbutamol Sulphate eq. to Salbutamol IP+Choline Theophylinate BP+Carbocisteine BP	1mg+50mg+50mg	Liquids Oral	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drug is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3560	Paracetamol IP+Chlorpheniramine Maleate IP+Caffeine Anhydrous iP+Phenylephrine HCl IP	500mg+2mg+30mg+10mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3561	Chlorpheniramine maleate IP+Vitamin C IP	2mg+30mg	Syrup	a, Pharmacodynamically irrelevant FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3562	Calcium Gluconate IP+Chlorpheniramine Maleate IP+Vitamin C IP	500mg+4mg+50mg	Solid Oral	a, Pharmacodynamically irrelevant- 1.Each ingredients have different indication. 2.This combination does not follow the concept and purpose of FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3566	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Caffeine IP	500mg+5mg+2mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3568	Chlorpheniramine Maleate IP+Paracetamol IP+Pseudoephedrine HCl IP+Caffeine (anhydrous) IP	2mg+500mg+60mg+30mg	Film Coated Tablets	a, 1.Pharmacodynamically irrationale FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Caffeine is CNS stimulant where as Pseudoephedrine leads to sedation.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3569	Guaifenesin IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP+Serratiopeptidase IP(as enteric coated granules)10000 SP Units	50mg+4mg +2mg+5mg +325mg+5 mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Guaiphenesin :a mucolytic which increases mucu secretion should not given in combination with antihistaminic with anti cholinergic properties because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. paracetamol : as cough and cold not allows accompanied by fever, addition of paracetamol express the consumers to the hepatotoxic effect of antipyretic unnecessarily 4. All ingredients have different therapeutic indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3570	Paracetamol IP+Pheniramine Maleate IP	500mg+12. 5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Both ingredients have different indications. 2. Misuse and toxicity of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3571	Paracetamol IP+Phenylephrine HCl IP+Caffeine anhydrous IP+Chlorpheniramine Maleate IP	500mg+5mg+15mg+2 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3575	Clobetasol Propionate+Ofloxacin+Ornidazole+Terbinafine HCl	0.05% w/w + 0.75% w/w + 2.0% w/w + 1.0% w/w	Cream base	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3579	Beclomethasone Dipropionate+Clotrimazole+Neomycin Sulphate	0.025% w/w + +1% w/w + 0.5% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3593	Betamethasone Dipropionate Ip Eq. to Betamethasone+Gentamicin Sulphate IP Eq. to Gentamicin+Miconazole Nitrate IP	0.05% w/w + 0.1% w/w + 2.0% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall be used for "steroid responsive dermatosis associated with mixed infection". FDC shall not be used continously for more than one week without re-evaluation by
3600	Betamethasone Valerate +Fusidic Acid+Gentamycin Sulphate+Tolnaftate+Iodochlorhydroxyquinoline(ICHQ)	1gm/0.61mg+20mg+1mg+10mg+10mg	Cream	a, Pharmacodynamically irrelevant- Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3603	Miconazole Nitrate + clorocresol + neomycin Sulphate	2.00%w/w + 0.10%w/w +0.50%w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3606	Beclomethasone Dipropionate IP+Clotrimazole IP+Neomycin Sulphate IP Eq. to Neomycin+Chloroc resol IP	0.025% w/w + 1.00% w/w + 0.50% w/w + 0.10% w/w	Cream base	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3615	Clotrimazole IP+Beclomethasone Dipropionate IP+Neomycin Sulphate IP eq. to Neomycin	1.00% w/w + 0.025% w/w + 0.5% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3622	Beclomethasone Dipropionate IP+Clotrimazole IP+Neomycin Sulphate IP Eq. to Neomycin+Chloroc resol IP	0.025% w/w + 1% w/w + 0.5% w/w +0.1% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3632	Clobetasol Proionate+Ofloxacin+Miconazole Nitrate+Zinc Sulphate	0.025%w/v +0.1%w/v+ 2.0%w/v+3. 0%w/v	Lotion	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3635	Betamethasone+Gentamycin Sulphate+Miconazole	0.10%w/w+ 0.10%w/w+ 2.0%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall be used for "steroid responsive dermatosis associated with mixed infection". FDC shall not be used continously for more than one week without re-evaluation by
3638	Ofloxacin+ Ornidazole + Terbinafine HCl + Clobetasol Propionate + Methyl Paraben + Propyl Paraben	0.75%w/w+ 2.0%w/w+1 .0%w/w+0. 05%w/w+0. 20%w/w+0. 02%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3641	beclomethasone Dipropionate + clotrimazole + neomycin sulphate + chlrocresol	0.025 % w/w + 1% w/w + 0.5 % w/w + 0.1 % w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3642	clobetasol propionate+ neomycin sulphate + clotrimazole	0.05%w/w + 0.5 % w/w + 1.0%w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3649	Clotrimazole IP+beclomethasone Dipropionate IP+Neomycin Sulphate IP+Methylparaben IP+Propylparaben IP	1% w/w + 0.025% w/w + 0.5% w/w + 0.15% w/w + 0.08% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3653	Ofloxacin IP +Ornidazole IP+Terbinafine HCl BP+Clobetasol Propionate BP+Methyl Paraben IP+Propyl Paraben IP	0.75% w/w + 2.0% w/w + 1.0% w/w +0.05% w/w + 0.20% w/w + 0.02% w/w	Topical Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3654	Clobetasole Propionate USP+Gentamicin IP+Miconazole Nitrate IP+Zinc Sulphate IP	0.05% w/w + 0.1% w/w + 2.0% w/w + 2.5%w/w	Topical Cream	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3659	Clobetasol Propionate USP+Miconazole Nitrate IP+Neomycin Sulphate IP+Chlorocresol IP	0.05% w/w + 2% w/w + 0.5% w/w + 0.1% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3660	Bethamethasone Valerate IP+Gentamicin Sulphate IP eq. to Gentamicin+Tolnaftate+Idochlorhydroxyquinoline IP+Borax BP+Chlorocresol IP	0.061% w/w + 0.1% w/w + 1.5% w/w + 1.5% w/w + 0.05% w/w + 0.1% w/w	Cream	a, Pharmacodynamically irrelevant- Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3663	terbinafine+ ofloxacin+ ornidazole + clobetasole propioanate + methylparaben + propylparaben	1% w/w + 0.75% w/w+ 2% w/w+ 0.05% w/w+ 0.20% w/w + 0.02% w/w	cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3669	ofloxacin + ornidazole+ terbinafine HCL+ clobetasole propionate + methylparaben+ propylparaben	0.75%w/w+ 2.0% w/w + 1.0%w/w+ .05% w/w+ .20% w/w+.02% w/w	cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3670	levocetirizine HCL+ ambroxol HCL+ phenylephrine HCL + paracetamol	2.5 mg+ 60 mg+ 5 mg+ 325 mg	tablets	a, 1 Dosing schedule is incompatible. 2. Patients may need only one or two ingredients and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3673	clobetasol propionate + gentamycin sulphate + miconazole nitarte+ borax+ chlorocreso	.05% w/w+ .1% w/w+ 2,0 % w/w+ 2.5 % w/w+ .05 % w/w+ .1% w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3678	Permethrin + Cetrimide IP + Menthol IP	1.0%w/w + 0.5%w/w + 1.0%w/w	Soap	a, 1.This FDC has no therapeutic value.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3679	Clobetasol Propionate BP+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP	0.05%w/w + 0.5% w/w + 2.0% w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3680	Clobetasol Propionate BP + Ofloxacin IP+Miconazole Nitrate IP+Zinc Sulphate BP	0.025%w/v + 0.1%w/v + 2.0%w/v +3.0%w/v	Topical Lotion	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3686	beclomethasone dippropionate+ clotrimazole + neomycin sulphate	0.025%w/w + 1% w/w + .5% w/w	cream	a,	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3687	Clotrimazole + beclomethasone dipropionate + neomycin sulphate	1% w/w.+ .025% w/w + .5% w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3691	Clobetasol Propionate + Clotrimazole + Neomycin Sulphate + Chlorocresol	0.05%w/w+ 1.00%w/w+ 0.5%w/w+0 .10%w/w	Topical Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3695	Clindamycin + Nicotinamide + Allantoin	1.0%w/w+4 .0%w/w+0. 50%w/w	Gel	a, Pharmacodynamically irrelevant- 1. Study did not show any added advantage of clindamycin phosphate 1% in combination with nicotinamide gel 4% over clindamycin phosphate 1 % alone. *Dos SK, Barbhuiya JN, Jana S, Dey SK Comparative evaluation of clindamycin phosphate. 1% and clindamycin phosphate 1% with nicotinamide gel 4% in the treatment of acne vulgaris. Year : 2003 | Volume : 69 | Issue : 1 | Page : 8-9*	d Re-examined and the Committee observed that Clindamycin 1% and nicotinamide 4% are comparable in some studies . However no data are available for their efficacy and safety, which needs to be established .
3701	Clotrimazole IP+Beclomethasone Dipropionate IP+Neomycin eq. to Neomycin	1.0% w/w + 0.025%w/w +0.5%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3707	Ofloxacin + Ornidazole + Terbinafine HCl+Clobetasol Propionate	0.75%w/w + 2%w/w + 1%w/w + 0.05%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3723	Clobetasole Propionate BP + Neomycin Sulphate IP + Miconazole Nitrate IP + Imidurea USPNF	0.05%w/w + 0.5%w/w + 2.0%w/w + 0.3%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3727	Clobetasol Propionate BP+Gentamicin+M iconazole Nitrate IP+Chlorocresol IP	0.05%w/w + 0.1%w/w + 2.0%w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3734	beclomethasone dipropionate + clotimazole + neomycin sulphate + iodochlorohydroxy quinone	.025% w/w + 10 % w/w + 5 % w/w + 1% w/w	cream	a, Pharmacodynamically irrelevant- Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

3736	clobetasol propionate + miconazole nitrate + neomycin sulphate + chlorocresol	.05% w/w + 2% w/w + .5 % w/w + .10 % w/w	topical cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3744	Clobetasol Propiionate BP+Ofloxacin IP+Miconazole Nitrate IP	0.025%w/w + 0.1%w/w + 2.0%w/w	Lotion	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3746	Neomycin Sulphate + Doxycycline HCl	100mg+100 mg	Powder	a, Pharmacodynamically irrelevant- 1. Patient may need only one ingredient 2. Drug misuse should not be there for diagnostic uncertainty 3. Inadvertent use of antimicrobials may lead to emergence of resistence 4. No published literature supporting this combination of products found	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3748	Ciprofloxacin Cl + Fluocinolone Acetonide + Clotrimazole + Neomycin Sulphate + Chlorocresol	0.5%w/w+0.25%w/w+1.0%w/w+0.5%w/w+0.1%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antibiotics , antifungal, steroid in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3.NO study is found supporting the combined use of ingredients in this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3749	Clobetasol Propionate + Ofloxacin + Ketoconazole + Zinc Sulphate	0.025%w/v+0.1%w/v+2.0%w/v+3.0%w/v	Lotion	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3752	Clobetasol Propionate + Neomycin Sulphate + Miconazole Nitrate + Chlorocresol	0.05%w/w+0.5%w/w+2%w/w+0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3757	Clotrimazole+Beclomethasone Dipropionate+Neomycin Sulphate+Methyl Paraben+Propyl Paraben	1%w/w+0.25%w/w+0.5%w/w+0.15%w/w+0.08%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3762	Fluocinolone Acetonide+Miconazole Nitrate+Neomycin Sulphate	0.025%w/w +2.0%w/w+ 0.5%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3768	Clobetasol Propionate+Neomycin Sulphate+Miconazole Nitrate	0.05%w/w+ 0.5%w/w+2 %w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3772	Clotrimazole+Beclomethasone Dipropionate+Neomycin Sulphate+Methyl Paraben+Propyl Paraben	1.00%w/w+ 0.025%w/w +0.500%w/w+0.150% w/w+0.080 %w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3777	Clobetasol Propionate+ Neomycin Sulphate+ Miconazole Nitrate	0.5%+0.5% +2.0%	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3782	Clobetasol Propionate+ Ofloxacin+ Miconazole Nitrate+ Zinc Sulphate+ P-Chlorocresol	0.025%w/w +0.1%w/w+ 2.0%w/w+3 .0%w/w+0. 1%w/w	Cream	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3795	Miconazole Nitrate IP+Gentamicin Sulphate IP+Clobetasone Butyrate BP	2.0%w/w + 0.1%w/w + 0.05%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3802	Clotrimazole IP+Beclomethasone Dipropionate IP+Gentamicin Sulphate IP	1.00%w/w + 0.025%w/w + 0.10%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3807	Clotrimazole IP+Beclomethasone Dipropionate IP+Clindamycin Phosphate BP	1%w/w + 0.025%w/w + 1%w/w	Cream for external use	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3810	Beclomethasone Dipropionate IP+Clotrimazole IP+Neomycin Sulphate IP Eq. to Neomycin	0.025%w/v + 1.0%w/v + 0.5%w/v	Lotion	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3814	Clotrimazole IP+Beclomethasone Dipropionate IP+Neomycin Sulphate IP	1.00%w/w + 0.025%w/w + 0.50%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3821	Betamethasone Valerate IP+Gentamicin Sulphate IP+Tolnaftate IP+Iodochlorhydroxyquinoline IP	0.50mg+1.00mg+15.00mg+15.00mg	Cream	a, Pharmacodynamically irrelevant- Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3822	Clotrimazole IP+Dexamethasone Acetate USP+Fradiomycin Sulphate JP (Neomycin Sulphate IP)+Methyl Paraben IP+Propyl Paraben IP	1.00%w/w + 0.10%w/w + 0.50%w/w + 0.08%w/w + 0.04%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3839	Clobetasol Propioinate BP+Miconazole Nitrate IP+Neomycin Sulphate IP	0.05%w/w + 2.0%w/w + 0.5%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3843	Clobetasol Propionate USP+Gentamicin Sulphate IP+Tolnaftate IP+Idochlorhydroxyquinone IP+Ketoconazole IP	0.05%w/w + 0.10%w/w + 1.00%w/w + 1.00%w/w + 2.00%w/w	Cream	a, Pharmacodynamically irrelevant- 1. Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC. 2. Combining two antifungal and two antimicrobial in the present FDC is scientifically irrelevant and is liable to be misused. It will lead to emergence of resistance and adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3844	Miconazole Nitrate IP+Fluocinolone Acetonide IP	2.00%w/w + 0.01%w/w	Ointment	a	c Re-examined and the Committee recommended that FDC in ointment dosage form is also recommended.
3847	Miconazole Nitrate IP+Neomycin Sulphate IP+Fluocinolone Acetonide IP	2%w/w + 0.5%w/w + 0.1%w/w	Topical Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3851	Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Clotrimazole IP+Chlorocresol IP	0.025%w/w + 0.5%w/w + 1%w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3852	Clobetrasol Propionate BP+Neomycin Sulphate IP+Miconazole Nitrate IP+Zinc Sulphate IP	0.05%w/w + 0.5%w/w + 2.0%w/w + 2.0%w/w	Cream	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3863	Flucinolone Acetonide IP+Gentamicin Sulphate IP+Clotrimazole IP	0.01%w/w + 0.10%w/w + 1.00%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3865	Clobetasol Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP	0.05%w/w + 0.5%w/w + 2.0%w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3875	Clobetasol Propionate IP+Neomycin Sulphate IP+Miconazole Nitrate IP	0.05%w/w + 0.50%w/w + 2.00%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3898	Ofloxacin+Ornidazole+Terbinafine HCl+Clobetasol Propionate	0.75%w/w+ 2.0%w/w+1.0%w/w+0.05%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3901	Ketoconazole+Beclomethasone+Neomycin	2%+0.025%+0.5%	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3908	Fluocinolone Acetonide+Miconazole Nitrate+Neomycin Sulphate	0.025%w/w +2.0%w/w+ 0.5%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3915	Allantoin+Dimethione+Urea+Propylene+Glycerin+Liquid paraffin	0.2%w/w+1.0%w/w+10.0%w/w+5.0%w/w+5.0%w/w+8.0%w/w	Cream	This FDC was earlier discussed by previous Committee on 22.8.2014 as under: Firm did not turn up for presentation. The FDC is not rational as ingredients present in the FDC have antagonistic functions. Further, there are no supporting documents to prove that the FDC is rational for the proposed indication. Hence, the committee did not recommend.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3929	Acriflavine HCl+Thymol+Cetrimide	0.12gm.+5.0mg+0.50gm	Cream	This FDC was earlier discussed by previous Committee on 22.8.2014 as under: Firm could not present any supporting data in respect of the rationality of the FDC. Moreover, the FDC is also not approved anywhere in the world. Hence, the committee did not recommend. There is no justification for addition of Thymol in this FDC (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3937	Betamethasone Dipropionate IP+Neomycin Sulphate IP+Tolnaftate USP+Iodo Chloro Hydroxy Quinoline IP+Cholorocresol IP	0.61mg+0.5mg+5mg+15mg+1.0mg	Topical Cream	a, Pharmacodynamically irrelevant- Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3938	Clobetasole Propionate Usp+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP	0.05%w/w + 0.5%w/w + 2.0%w/w + 0.1%w/w	Topical Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3971	Ofloxacin IP+Ornidazole IP+Terbinafine HCL BP+Clobetasol Propionate BP+Methyl Paraben IP+Propyl Paraben IP	0.75%w/w + 2.0%w/w + 1.0%w/w + 0.05%w/w +0.20%w/w + 0.02%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
3974	Clobetasol Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP	0.05%w/w + 0.5%w/w 2.0%w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

3994	Clotrimazole IP+Clindamycin Phosphate+Benzyl Alcohol IP	2%w/w + 2%w/w + 2%w/w	Gel	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient.	d it was observed that this FDC is not for the dermatological use but under the category Gyne.The FDC is already recommended for coducting clinical trial by the previous Committee.
3995	Clotrimazole IP+beclomethasone Dipropionate IP+Neomycin Sulphate IP+Methylparaben IP+Propylparaben IP	1%w/w + 0.025%w/w + 0.5%w/w + 0.15%w/w + 0.08%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3996	Clobetasol Propionate BP+Miconazole Nitrate IP+Neomycin Sulphate IP+Glycerin IP+Cetrimide IP	0.05%w/w + 2%w/w + 0.5%w/w + 3%w/w + 0.6%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
3998	Beclomethasone Dipropionate USP+Clotrimazole IP+Neomycin Sulphate IP+Chlorocresol IP	0.025%w/w + 1%w/w + 0.5%w/w + 1.0%w/w	Topical cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4002	Clobetasol Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP	0.05%w/w + 0.1%w/w + 2.0%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4004	Beclomethasone Dipropionate +Gentamicin Sulphate IP+Miconazole Nitrate IP	0.03%w/w + 0.10%w/w + 2%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4005	Clotrimazole+Beclomethasone Dipropionate+Neomycine sulpahte	1.0%w/w+0.025%w/w+0.5%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

4006	clobetasol Propionate+Neomycin Sulpahte+Miconazole Nitrate+Clotrimazole	0.05%w/w+0.1%w/w+2.0%w/w+1.0%w/w	topical cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antifungal drugs in the present FDC has no scientific rationality as NO study is found supporting this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4007	Fluocinolone Acetonide+Neomycin sulpahte+Clotimazole	0.01%+0.5%+1.0%	topical cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4010	Ketoconazole+Tea Tree oil+Allantion+zinc Oxide+Aloe Vera+Jojoba oil+Lavander oil+Soap noodles	2.0%w/w+1.5%w/w+0.2%w/w+0.5%w/w+0.5%w/w+1.0%w/w+1.0%w/w+0.25%w+100%w/w	External	a, Pharmacodynamically irrelevant as the combination does not give any therapeutic benefit. Use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4018	Clobetasol Propionate IP+Ofloxacin IP+Ornidazole IP+Terbinafine HCL IP	0.05%w/w + 0.75%w/w + 2.00%w/w + 1.00%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4025	Ofloxacin IP+Ornidazole IP+Terbinafine HCL BP+Clobetasol Propionate BP+Methyl Paraben IP+Propyl Paraben IP	0.75%w/w + 2.00%w/w + 1.00%w/w + 0.05%w/w + 0.20%w/w + 0.02%w/w	Cream	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining two antimicrobial drugs in the present FDC is liable to be misused and emergence of resistance and adverse effects. 3 NO study is found supporting the combined use of two antibiotics in this FDC	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4027	Clobetasol Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP+Zinc Sulphate	0.05%w/w + 0.5%w/w + 2.00%w/w + 2.00%w/w	Cream	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4036	Clobetasol propionate+Miconazole nitrate+Neomycin sulpahte+chlorocresol	0.05%w/w+2.0%w/w+0.5%w/w+0.1%w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4040	Miconazole nitrate+Neomycin Sulpahte+clobetasol propionate+chlorocresol	2%w/w+0.5%w/w+0.05%w/w+0.1%w/w	Topical cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4041	Beclomthasone Dipropionate+Clotrimazole+Chloramphenicol+Gentamycin Sulpahte+Lignocaine Hcl	0.025%w/v+1%w/v+5%w/v+0.3%w/v+2%w/v	cream	a	c Re-examined and the Committee recommended that FDC shall be used for "steroid responsive dermatosis associated with mixed infection". FDC shall not be used continously for more than one week without re-evaluation by
4042	Beclomethasone dipropionate+clotrimazole+Neomycin sulphate+Methylpraben+Propylparaben	0.025%w/w+1.0%w/w+0.25%w/w+0.025%w/w	cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4066	Clotrimazole IP+Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Methyl Paraben IP+Propyl Paraben IP	1.0%w/w + 0.025%w/w + 3500 units per g+0.15%w/w + 0.08%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4100	Clobetasole Propionate USP+Neomycin Sulphate IP+Miconazole Nitrate IP+Chlorocresol IP	0.05% w/w + 0.5%w/w + 2.0%w/w + 0.10%w/w	Ointment	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

4101	Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Tolnaftate USP+Iodochlorhydroxyquinoline IP+Chlorocresol IP	0.25mg+0.5mg+15mg+15mg+1mg	Ointment	a	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4106	Betamethasone Di-Propionate eq. to Betamethasone BP+Gentamycin Sulphate eq. to Gentamycin BP+Miconazole Nitrate eq. to Miconazole BP	0.05% w/w + 0.1% w/w + 2% w/w	Topical Cream	a	c Re-examined and the Committee recommended that FDC shall be used for "steroid responsive dermatosis associated with mixed infection". FDC shall not be used continously for more than one week without re-evaluation by
4107	Betamethasone Di-Propionate eq. to Betamethasone BP+Gentamycin Sulphate eq. to Gentamycin BP+Zinc Sulphate IP+Clotrimazole IP+Chlorocresol IP(As preservative)	0.05% w/w + 0.1%w/w + 2.5% w/w + 1.0% w/w + 0.1% w/w	Topical Lotion	a, Pharmacodynamically irrelevant- No study is found supporting the combined use of this FDC as use of zinc sulphate in Topical form is not scientifically proven (09.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4121	Clobetasole Propionate USP+Clotrimazole IP+Neomycin Sulphate IP	0.005% w/v + 2.0% w/v + 3500 units/ml	Suspension	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4132	Benfothiamine+Vitamin A Acetate IP+Riboflavin IP+Pyridoxine Hcl IP+Cyanocobalamin IP+Ascorbic Acid IP+Vitamin D3 IP+Vitamin E Acetate IP+Folic acid IP+Nicotinamide IP+Calcium Pantotenate IP+Biotin USP+Selenium Dioxide USP+Chromium Picolinate USP+Magnesium Oxide USP+Colliodal Silicon Dioxide IP eq. to Silica+ Potassium Iodine	2mg+5000 IU+10mg+2mg+7.5mcg+75mg+400 IU+15mg+1.5mg+50mg+50mg+150mcg+70mcg+250mcg+30mg+2.5mg+1mg+150mcg+2mg+63mg+25mcg	Tablets	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile.	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b

4143	Clobetasol Propionate BP+Neomycin Sulphate IP+Clotrimazole IP	0.05%w/w+ 0.50%w/w+ 1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4155	Paracetamol IP+Phenyephrine Hydrochloride IP+Caffeine (anhydrous) IP	500mg+2.5 mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinedically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4161	Paracetamol IP+Caffeine IP+Chlorpheniramine Maleate IP	325mg+30 mg+2mg	Uncoated tablets	a, Pharmacodynamically irrelevant- 1. Subtherapeutic dose of paracetamol. 2. Caffeine causes stimulation whereas, Chlorpheniramine causes sedation.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4162	Paracetamol IP+Promethazine Hydrochloride IP	250mg+2.5 mg	Suspensi on	a, 1. Pharmacodynamically irrelevant. 2. Both ingredients have different indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4169	Borax BP+Boric acid IP+Naphazoline Hydrochloride BP+Menthol IP+Camphor IP66+Sodium methyl hydroxy benzoate eqvi. IP to methyl hydroxy banzoate	0.050%w/v + 3% w/v + 3% w/v + 0.0025%w/v + 0.0025w/v + 0.023%w/v	Eye Drops	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacologica profile susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4170	Beclomethasone dipropionate IP+Clotrimazole IP+Lignocaine Hydrochloride IP+Chloramphenicol IP (In propylene glycol IP and Glycerine IP base)	0.025%w/v + 1%w/v + 2%w/v + 5%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4176	Hydrocortisone acetate IP+Atropine sulphate IP+Chlorbutol IP	0.5%w/v + 1%w/v + 0.5%w/v	Eye Drops	a,	c, The Committee re-examined the FDC and recommended for use only - "To be used in condition of severe Acute Uveitis in adults only".
4177	Codeine phosphate IP+Chlorpheniramine Maleate IP	10mg+4mg	Syrup	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4179	Bromhexine Hydrochloride IP+Dextromethorphan Hydrobromide IP	4mg+5mg	Syrup	a, Pharmacodynamically irrelevant- 1. Dextromethorphan: it decreases the cough impulse so expulsion of secretion would be hampered 2. Bromhexine:a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4182	Paracetamol IP+DL-Methionine BP	325mg+50 mg	Uncoated Tablets	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4204	Salbutamol(as Salbutamol Sulphate IP)+Hydroxyethyltheophylline IP 85(Etofylline)+Bromhexine Hydrochloride IP	2mg+200mg+8mg	Uncoated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4207	Paracetamol IP+DL-Methionine BP	125mg+12.5mg	Suspension	a, 1.Pharmacodynamically irrelevant - misuse and overuse of one of the ingredients of FDC in case it is not indicated. 2.There is no recent peer reviewed scientific data regarding efficacy of Methionine in preventing paracetamol toxicity in FDC (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4213	Chloramphenicol IP+Beclomethasone Dipropionate IP+Clotrimazole IP+Lignocaine Hydrochloride IP	5%w/v + 0.025%w/v + 1%w/w + 2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4214	Salbutamol IP+Etofyline+ Bromhexine HCl IP	2mg+200mg+8mg	Uncoated Tablets	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4221	Dextromethophan Hydrobromide IP+Chlopheniramine Maleate IP+Bromhexine Hydrochloride IP	10mg+2mg+4mg	Uncoated Tablets	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4228	Guaifenesin IP+Bromhexine Hydrochloride IP+Phenylephrine Hydrochloride IP+Chlopheniramine Maleate IP+Paracetamol IP	100mg+8mg+5mg+2mg+325mg	Tablets	a, Pharmacodynamically irrelevant- 1. Guaiphenesin :a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. paracetamol : as cough and cold not allows accompanied by fever, addition of paracetamol express the consumers to the hepatotoxic effect of antipyretic unnecessarily 4. All ingredients have different therapeutic indications.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4237	Menthol IP+Anesthetic Ether IP	0.1% w/v + 1% v/v	Spirit	a, Pharmacodynamically irrelevant- 1. No published literature supporting the use of combination.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4242	Ferric ammonium Citrate IP+L-Lysine Hydrochloride USP+Niacinamide IP+D-Panthenol IP+Pyridoxine Hydrochloride IP+Folic Acid IP+Cyanocobalamine IP+Elemental Zinc	150mg+50mg+45mg+5mg+1.5mg+1mg+7.5mg+10mg	Syrup	a, • Overdose of vitamin B12	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
4244	Dextrometharphan Hydrobromide IP+Chlopheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	10mg+4mg+240mg+240mg+1.25mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4256	Clobetasol+Neomycin+Clotrimazole	0.05%w/w + 0.50%w/w + 1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

4262	Beclomethasone dipropionate IP+Miconazole Nitrate IP+Neomycin sulphate IP+Chlorocresol (as preservative) IP	0.025%w/w + 2%w/w + 0.5%w/w + 0.250%w/w	Ointment	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4264	Clobetasole Propionate BP+Neomycin sulphate IP+Miconazole Nitrate IP+Chlorocresol (As Preservatives) IP Chlorocresol (as preservative) IP	0.05%w/w + 0.5%w/w + 2%w/w + 0.1%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4269	Bromhexine hydrochloride IP+Guaifenesin IP+Phenylephrine hydrochloride IP+Chlorphenirami ne Maleate IP+Paracetamol IP	8mg+100m g+5mg+2m g+325mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Bromhexine :a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4270	Ergotamine Tartrate IP+Belladona dry extract IP+Caffeine (anhydrous) IP+Paracetamol IP	1mg+10mg +100mg+25 0mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Belladona dry extract not indicated for migraine. 2. Dose of paracetamol is subtherapeutic.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4275	Dextromethorphan hydrobromide IP+Chlorphenirami ne Maleate IP	10mg+4mg	Syrup	a	C Inadvertatntly included as "a". Same is approved by DCG(I)

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4277	Phenytoin IP+Phenobarbitone sodium IP	100mg+50 mg	Uncoated Tablets	a, Pharmacodynamically irrelevant. 1. Phenobarbital will decrease the level or effect of phenytoin by affecting hepatic enzyme CYP2C9/10 metabolism. Significant interaction possible. 2. Phenobarbital decreases levels of phenytoin by increasing metabolism. 3. Phenobarbital may occasionally not change or even increase (via competitive inhibition) phenytoin levels. http://reference.medscape.com/drug-interactionchecker.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4284	Imipramine hydrochloride IP+Diazepam IP	25mg+2mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Diazepam and imipramine both increase sedation. 2. Potential for interaction. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4296	Nimesulide BP+Serratiopeptidase (enteric coated)(30,000 serratiopeptidase units) (30,000 serratiopeptidase units)	100mg+15 mg	Film Coated Tablets	a, 1. Safety concern with nimesulide 2.No evidence to support that Serratiopeptidase offer any particular advantage over Nimesulide. 3. On the other hand, the patient is exposed to greater risk of gastrointestinal (GI) irritation and serious bleeding from unsuspected peptic ulceration. *Chandler S. Gautam, Lekha Saha. Fixed dose drug combinations (FDCs): rational or irrational: a view point Br J Clin Pharmacol / 65:5 / 795-796.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4299	Gliclazide IP+Metformin HCL IP	40mg+400 mg	Uncoated Tablets	a, Sub-therapeutic dose of metformin.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4307	Clotrimazole IP+Neomycin Sulphate IP eqvt. To Neomycin+Beclomethasone dipropionate IP	1%w/w + 0.5% w/w + 0.025%w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.

4317	Paracetamol IP+Ambroxol HCL IP+Phenylephrine HCL IP+Chlorphenirami ne Maleate IP	250mg+15 mg+5mg+2 mg	Syrup	a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4320	Paracetamol IP+ Ambroxol Hydrochloride IP+ Phenylephrine Hydrochloride IP+Chlorphenirami ne Maleate	125mg+7.5 mg+2.5mg+ 1mg	Drops	a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4322	Paracetamol IP+Ambroxol Hydrochloride IP+ Phenylephrine Hydrochloride IP+Chlorphenirami ne Maleate	500mg+30 mg+10mg+ 2mg	Film Coated Tablets	a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4344	Dextromethorphan Hydrobromide IP+Chlorphenirami ne Maleate IP+Pheylephrine Hydrochloride IP+Paracetamol IP	5mg+1.5mg +2.5mg170 mg	Oral	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4345	Oflaxacin IP+ Ornidazole IP	50mg+125 mg	Suspensi on	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4357	Albuterol Sulphate IP eq. to Albuterol+ Etofylline IP+ Bromhexine HCl IP+ Menthol IP	1mg+ 50mg+ 4mg+1mg	Liquid	a, 1. Etofylline is a narrow therapeutic indexed drug and requires close monitoring. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4358	Albuterol Sulphate IP eq. to Albuterol+ Bromhexine HCl IP+ Theophylline anhydrous IP	2mg+8mg+ 100mg	Hard Gelatin Capsules	a, 1. Theophylline is a narrow therapeutic indexed drug and requires close monitoring. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4359	Clobetasole Propionate USP+Gentamycin Sulphate IP eq. to Gentamycin+Miconazole Nitrate IP+Chlorocresol (as Preservative) IP	0.05% w/vw + 0.10% w/w + 2.00% w/w + 0.10% w/w	Cream	a	c Re-examined and the Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
4385	Salbutamol (As Salbutamol Sulphate IP)+ Hydroxyethyltheophylline IP 85' (Etofylline)+ Bromhexine HCl IP	1mg+50mg +4mg	Syrup	a, 1. On the basis of current scientific understanding the FDC is pharmacodynamically irrelevant. 2. Use of Mucolytic alongwith anti-asthamatic drugs is liable to be misused as expectorant and exposing the patients unnecessary to the drugs and their adverse effects.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4403	Phenylephrine HCl IP+Paracetamol IP+Chlorpheniramine Maleate IP+Caffeine Anhydrous IP	5mg+325mg+2mg+30 mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4416	Paracetamol Ip+Ambroxol Hcl IP+Phenylephrine Hcl IP+Chlorphenirami ne Maleate IP	125mg+15 mg+5mg+2 mg	Syrup	a, Pharmacodynamically irrelevant 1. Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4417	Phenylephrine HCl IP+Paracetamol IP+Chlorphenirami ne Maleate IP+Caffeine Anhydrous IP	5mg+325m g+2mg+15 mg	Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4431	Codeine Phosphate IP+Chlorphenirami ne MaleateIP	10mg+4mg	Oral Liquid	1 Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.There is a high risk of abuse potential of this formulation in indian scenerio.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4443	Levocetirizine HclIP+Phenylephri ne Hcl IP+Paracetamol IP+Caffeine (Anhydrous)	2.5mg+10m g+325mg+3 0mg	Uncoated tablets	a, 1. Pharmacodynamically irrelevant-Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4448	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Syrup	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalone 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4472	Levocetirizine HCl IP+Ambroxol Hcl IP+Guaifenesin IP+Phenylephrine Hcl IP	0.8mg+15mg+50mg+5mg	Oral Suspension	a, Pharmacodynamically irrelevant- 1.Patients may not need all the ingredients and use of FDC may lead to misuse and adverse effects. 2.Pharmacokinetically irrelevant-different dosing shedule.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4473	Paracetamol IP+Phenylephrine Hcl IP+Levocetirizine HCl IP+Sodium Citrate IP	250mg+5mg+1.25mg+60mg	Oral Suspension	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4482	Paracetamol IP+Propyphenazone IP+Caffeine (Anhydrous) IP	300mg+150mg+50mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Paracetamol dose is subtherapeutic. 2. Suceptibility of adverse drug reaction is very high 3. Misuse potential.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4485	Chlorpheniramine Maleate IP+Phenylephrine Hcl IP+Guaifenesin IP+Dextromethorphan Hcl IP	4mg+5mg+100mg+10mg	Liquid Orals	a, I Dosing schedule is incompatible. 2. Both the ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4492	Phenytoin Sodium IP+Phenobarbitone IP	100mg+30mg	Uncoated tablets	a, Pharmacodynamically irrelevant. 1. Phenobarbital will decrease the level or effect of phenytoin by affecting hepatic enzyme CYP2C9/10 metabolism. Significant interaction possible. 2. Phenobarbital decreases levels of phenytoin by increasing metabolism. 3. Phenobarbital may occasionally not change or even increase (via competitive inhibition) phenytoin levels. *http://reference.medscape.com/drug-interactionchecker.*	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4527	Guaifenesin IP+Diphenhydramine Hcl IP+Bromhexine Hydrochloride IP+Phenylephrine Hydrochloride IP	50mg+10mg+4mg+5mg	Syrup	a, Pharmacodynamically irrelevant- • Anticholinergic property of diphenhydramine will lead to drying up of secretions while mucolytics increase.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4535	Paracetamol IP+Caffeine (Anhydrous) IP+Chlorpheniramine Maleate IP	325mg+20mg+2mg	Uncoated tablets	a, Pharmacodynamically irrelevant- 1. Paracetamol dose is subtherapeutic. 2. Potential for drug-drug interaction.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4536	Dried Alumnium Hydroxide Gel IP+Propantheline Bromide IP+Diazepam IP	100mg+15mg+2mg	Capsules	a, Pharmacodynamically irrelevant- 1. No published literature supporting the FDC. 2. In present scenario Propanthaline has safety concerns. 3. Use of diazepam is irrational.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4570	Bromhexine Hcl IP+PhenylephrineHcl IP+Chlorpheniramine Maleate IP+Paracetamol IP	8mg+5mg+2mg+325mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Bromhexine :a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Paracetamol dose is subtherapeutic and potential misuse in FDC formualtion is likely to be hepatotoxic .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4571	Bromhexine Hcl IP+PhenylephrineHcl IP+Chlorpheniramine Maleate IP+Paracetamol IP	4mg+2.5mg+2mg+125mg	Suyrup	a, Pharmacodynamically irrelevant- 1. Bromhexine :a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3. Potential misuse in FDC formualtion is likely to be hepatotoxic .	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4573	Beclomethasone Dipropionate+Clotrimazole+Gentamicin Sulphate+Iodo-Chlorhydroxyquinoline	0.025% w/w + 1% w/w + 0.1% w/w + 1% w/w	Cream	a, Pharmacodynamically irrelevant- Combining iodochlorohydroxyquinone in the present FDC is not preferred due to adverse effects and availability of better safer drugs. NO study is found supporting the combined use of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4590	Paracetamol IP+Phenylephrine Hcl IP+Chlorpheniramine maleate IP+Caffeine (anhydrous) IP	325mg+10 mg+2mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4591	Paracetamol IP+PhenylephrineHcl IP+Caffeine (anhydrous) IP	325mg+10 mg+32mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4592	Bromhexine Hcl IP+Phenylephrine Hcl IP+Guaifenesin IP+Chlorpheniramine Maleate IP+Paracetamol IP	8mg+5mg+ 100mg+2mg+325mg	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Guiaphenesin: a mucolytic which increases mucus secretion should not given in combination with antihistaminic with anti cholinergic properties, because due to anti cholinergic properties mucus secretions is dried up. 2. Chlorpheniramine :H1 antagonist are said to decrease rhinorrhea but the drying effect may do more harm because of their tendency to induce somnolence 3.Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility 4.Misuse of paracetamol.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4623	Betamethasone Propionate IP eq. to Betamethasone+Gentamycin Sulphate IP eq. to Gentamycin+Miconazole Nitrate IP	0.05% w/w + 0.1% w/w + 2% w/w	External Preparation	a	c Re-examined and the Committee recommended that FDC shall be used for "steroid responsive dermatosis associated with mixed infection". FDC shall not be used continously for more than one week without re-evaluation by

4643	Ofloxacin IP+Ornidazole IP	50mg+125 mg	Oral suspension	a, 1. Both ingredients of the FDC have different therapeutic indcations 2.Inappropriate use of ornidazole will lead to emergence of antibiotic resistance against quinalones. 3. Safety concerns in paediatric patients.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4644	Glibenclamide IP+Metformin Hcl IP (In sustained release form)+ Pioglitazone Hcl IP eq. to Pioglitazone	5mg+500mg+15mg	Uncoated bilayered tablets	a, 1. There is no published literature supporting this FDC. 2. The Pioglitazone has safety concerns.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4651	Telmisartan + Metformin	40 mg + 1000 mg	Tablet	a, Pharmacodynamically irrelevant as no study supports this combination.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
4873	Allantoin BP+ Vitamin-E Acetate+ Tea tree oil	0.25%w/w +0.25w/w+ 0.50%w/w	Medicated Soap	a,	c Re-examined and the Committee recommended FDC as cleansing agent for acne.
4874	Allantoin BP+Vitamin-E Acetate+Tea tree oil+Titanium Dioxide IP	0.20%w/w+ 0.25%w/w+ 0.25%w/w+ 0.50%w/w	Medicated Soap	a,	c Re-examined and the Committee recommended FDC as cleansing agent for acne.
4906	Ammonium Citrate+Vitamin B 12+Folic Acid+Zinc Sulphate Monohydrate	160mg+7.5 mg+0.5mg+ 20.61mg	Soft Gelatin Capsules	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. ingredients susceptible to pharmaceutically incompatibility	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

4981	methylcobalamin+ folic acid+ pyridoxine HCL+ inositol + alpha lipoic acid+ chromium+ vanadyl sulphate+ seleniuos acid+ zinc sulphate	2000mcg+ 1500mcg 3 mg+ 200 mg+ 200 mg+ 200 mcg+ 10 mcg+ 100 mc+ 10 mg	hard gelatin capsule	a, 1. Over dose of metylcobalamin 2. Multiple ingredient susceptible to pharmaceutically incompatibility and susceptible dose	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
4988	levothyroxine Sodium+ pyridoxineHCL+ nicotinamide	25 mg+ 1 mg+ 25 mg	tablets	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
5035	benfotiamine+ metformin HCl	75 /100 mg+ 500 mg	tablets	This was discussed by previous Committee on 27.08.14 as under- The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
5135	beta carotene + nicotinamide + pyridoxine hydrochloride+ cholecalciferol + folic acid+ cyanocobalamin +light magnesium oxide+ zinc sulphate+ manganese sulphate+ copper sulphate+ chromium picolinate+ selenious acid + sodium molybdenum+	30 mg+ 1.5 mg+ 1000 IU+ 1000 mcg+ 5 mcg + 100 mg+ 22.5 mg + 2.5 mg+ 2 mg + .2 mg .055 mg+ .05 mg + .01 mg + 100 mg	soft gelatin capsules	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility 3.Dose of Folic acid & nicotinamide sub-therapeutic.	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
5158	pyridoxine HCL+ niacinamide + thiamine HCL+ calcium pantothenate+ ascorbic acid+ methionine+	9mg+ 22.5 mg+ 2.75 mg+ 2.5 mg+ 37.5 mg+ 2 mg	syrup	a, 1. exceeds therapeutic dose of pyridoxine. 2. ingredients susceptible to pharmaceutically incompatibility 3. dose selection is not accurate	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b

5275	Biotin USP+Vitamin B6 IP+Niacinamide IP+Folic Acid IP+Cyanocobalamin IP+Calcium Pantothenate IP+Zinc Sulphate IP+Lactic Acid	100mcg+1.5mg+45mg+5mcg+20mcg+50mg+100 Lacs spores	Film Coated Tablets	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile susceptible to pharmaceutically incompatibility	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
5617	Calcium Orotate+Zinc Sulfate+Folic Acid+Cyanocobalamin	740mg+7.5mg+50mcg+0.5mcg	Tablets	a, Pharmacodynamically irrelevant- 1.Each ingredients have different indication. 2.This combination does not follow the concept and purpose of FDC 3. Sub-therapeutic dose of Vit-B12	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
5659	Protein Hydrolysate+Iron Choline Citrate+Thiamine HCl+Riboflavin+Pyridoxine HCl+Folic Acid+Cyanocobalmain	500mg+150mg+0.5mg+0.5mg+0.25mg+25mcg+0.5mcg	Syrup	a, sub-therapeutic dose of vitamin B12	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
5807	Proteine Hydrolysate eq. to Nitrogen+Iron Choline Citrate eq. to elemental Iron+Zinc Sulphate IP+Niacinamide IP+Thiamine HCl IP+Riboflavin IP+Pyridoxine HCl IP+Cyanocobalamin IP	10mg+20.0mg+15mg+7.5mg+0.5mg+0.5mg+0.25mg+0.25mcg	Syrup	a, sub-therapeutic dose of vitamin B12	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
5837	Thyroid IP'85 +Thiamine Mononitrate IP+ Riboflavin IP+ Pyridoxine HCl IP+ Calcium Pantothenate IP+ Tocopheryl Acetate IP+Nicotinamide IP	15mg+2.5mg+2.5mg 1mg+ 5mg+10mg+25mg	Film Coated Tablets	a, No clinical studies found supporting the use of this combination	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
5958	Ascorbic Acid IP+ Manadione Sodium Bisulphate+ Rutin NF, XI + Dibasic Calcium Phosphate IP + Adrenochrome Mono Semicarbazone	150mg+10mg+ 50mg+ 132mg+0.5mg	Uncoated Tablets	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Multiple ingredients with diverse pharmacological profile.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

5973	Lactic Acid Bacillus + Folic Acid IP+ Cyanocobalamin IP	180 Million +1500 mcg +15mcg	Uncoated Dispersible tablet	a, 1. Pharmacodynamically irrelevant. 2. Role of lactic acid in this combination is not clear.	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b
6189	Phenylephrine Hcl IP+Chlorpheniramine Maleate IP+Paracetamol IP+Bromhexine Hcl IP	2.5mg+1.0 mg+125mg +4mg	Syrup	a, Pharmacodynamically irrelevant. 1.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions. 2.Dosing schedule is incompatible.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
6191	Phenylephrine Hcl IP+Chlorpheniramine Maleate IP+Paracetamol IP+Bromhexine Hcl IP+Caffeine (anhydrous) IP	5mg+2mg+ 500mg+8mg+15mg	Uncoated Caplet	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse. 3.Dosing shedule of the ingredients is incompatible. 4.Mucolytic increases mucus secretion and antihistaminic with anti cholinergic properties dry up secretions.	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
6198	Clotrimazole IP+Beclomethasone Dipropionate IP+Lignocaine HCl IP+Ofloxacin IP+Acitic Acid IP+(Preservatives) Sodium Methyl Paraben IP+Propyl Paraben IP	1% w/v + 0.025% w/v + 2% w/v + 0.3% w/v + 2.0% w/v + 0.1% w/v + 0.02% w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required (07.01.2016).	The replies /clarifications wherever available from firms and earlier data submitted by them were thoroughly examined. The Committee obesrved that data submitted and available peer reviewed scientific evidences do not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
6211	Thiamine Mononitrate IP+Riboflavin Sodium Phosphate eq. to Riboflavin (Vitamin B2)+ Nacinamide IP+ Pyridoxine Hcl IP+ Vitamin A concentrate (Oily form) (As Palmitate)+ Cholecalciferol + Ascorbic Acid IP + D-Panthenol IP +Tocopheryl Acetate IP	2mg+1mg +10mg +1.0mg +3000 IU+ 400 IU+ 40mg +3.0mg +5.0 IU	Oral	a, Pharmacodynamically irrelevant- 1 Multiple ingredient of diverse group 2 Sub therapeutic combinations 3 Pharmacodynamic role is not clear	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category b

6214	Zinc Sulphate IP eq. to elemental Zinc+Vitamin A Palimate IP+Vitamin D3 IP+Vitamin B1 IP+Vitamin B2 IP+Vitamin B6 IP+Niacinamide IP	25mg+5.7mg+1600 IU+200 IU+1.5mg+1.5mg+1.0mg+15mg	Oral	a, Pharmacodynamically irrelevant- 1. Therapeutic area not clear 2. Combination irrational. 3. Element are of different class hence have diverse activity	b. The matter was examined.The Committee opined that this is a vitamin preparation and shall be discussed seperately with other vit. Preparations .Presently this FDC may be categorised under category'b'

77	Acetaminophen IP+Nimesulide BP+Chlorzoxazone USP	325mg+100mg+250mg	Uncoated Tablets	a, 1.Nimesulide in combination has potential of misuse and have documanted safety concern. 2.Pharmacodynamically irrationale FDC as two ingredients have same mechanism of action.	subjudice
72	Acetaminophen + Nimesulide + Chlorzoxazone USP	325mg+100mg+250mg	Uncoated Tablets	a, 1.Nimesulide in combination has potential of misuse and have documanted safety concern. 2.Pharmacodynamically irrationale FDC as two ingredients have same mechanism of action.	subjudice
3026	Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	15mg+5mg+2.5mg	Syrup	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	C Inadvertantly included as "a". Same is approved by DCG(I)
3369	Dextromethorphan Hydrobromide+Chlorpheniramine Maleate+Phenylephrine Hydrochloride	5mg+5mg+5mg	Oral Liquid	a, 1 Dosing schedule is incompatible. 2. Ingredients will aggravate the adverse effects of sedation and drowsiness and also will interefere with the reflexes. 3.Centrally acting anti-tussive not to be combined with anti-histaminic drug.	C Inadvertantly included as "a". Same is approved by DCG(I)
2554	Nimesulide BP+ Chlorpheniramine Maleate IP+ Phenylephrine HCL IP+ Caffeine IP	100mg+4mg+10mg+30mg	Uncoated Tablets	a, 1.Pharmacodynamically and phamacokinetically irrational FDC. 2.Patients may need only one ingredient and use of FDC may lead to misuse.	subjudice
3205	Nimesulide+Chlorpheniramine maleate+Phenylephrine HCl+Caffeine anhydrous	100mg+4mg+10mg+30mg	Uncoated tablet	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesulide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	subjudice
2570	Nimesulide+Pimeylephrine HCl+Chlorpheniramine Maleate+Caffeine	100mg/100mg10mg/5mg+4mg/4mg+30mg/30mg	Tablets	a, 1. Nimesulide in combination has potential of misuse in indications for allergic conditions. Users who may not be aware of this paracetamol content and may accidentally overdose when they take the multi- ingredient product with other medicines also containing paracetamol. 2. There is pharmacokinetic incompatibility among the drugs. 3.Nimesulide has documanted safety concern. 4. Hepatotoxic potential of both the drugs Eccles, R., Fietze, I. and Rose, U.-B. (2014) Rationale for Treatment of Common Cold and Flu with Multi-Ingredient Combination Products for Multi-Symptom Relief in Adults. Open Journal of Respiratory Diseases, 4, 73-82.	subjudice
644	Paracetamol IP+ Lignocaine Hydrochloride IP + Benzyl Alcohol IP	150mg+1.0%+1%v/v	Injection	a, 1.Pharmacodynamically irrelevant FDC. 2.Hypersensitivity to lignocaine is also a safety concern.	subjudice

(C.K. Kokate)

Minutes of the Meeting of Expert Committee held on 4.01.2016 and 05.1.2016 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
3. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
4. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
5. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
6. Dr. J. C. Suri, Prof., Department of Pulmonary, VMCC & Safdarjung Hospital, New Delhi
7. Dr. B. Gupta, Prof., Dept. of Medicine, Hindu Rao Hospital, New Delhi

Dr. C.L. Kaul, Former Director, NIPER and Dr. Sanjeev Sinha, Prof., Dept. of Medicine AIIMS could not attend the meeting.

The Chairman welcomed the members of the Committee and apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health

& Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under **category 'a'** and accordingly show cause notices have been issued to the concerned manufacturers.
2. FDCs requiring further deliberation with subject experts were categorized under **category 'b'** and further deliberations are in progress.
3. FDCs considered as rational by the Committee were categorized under **category 'c'** and accordingly approval letters have been issued to the concerned manufacturers.
4. FDCs requiring further generation of data were categorized under **category 'd'** and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee and have been found to be irrational. Based on the recommendations of the Committee, Show cause notices were served to the applicant firms as to why manufacturing license in respect of such FDCs may not be deemed to have been cancelled. Now, the firms have submitted their replies which need to be examined by the Committee.

The detailed therapeutic category-wise agenda containing FDCs related to Pulmonary category was placed before the Committee. The Committee also signed the No Conflict of Interest. The Committee discussed each FDC and made their recommendations are enclosed.

The meeting ended with the vote of thanks to the Chair.

5/1/16
(Dr. R.K. Khar)

5/1/16
(Dr. Bikash Medhi)

5/1/16
(Dr. C.D. Tripathi)

(Prof. Sanjay Singh)

(Dr. J. C. Suri)

5/1/16
(Dr. B. Gupta)

(Dr. Sanjeev Sinha)

5.1.16
(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 6.1.2016 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
3. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
4. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
5. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
6. Dr. C.L. Kaul, Former Director, NIPER
7. Dr. Richa Dewan, Prof. & Head, Dept. of Medicine, MAMC, New Delhi

Dr. Sanjeev Sinha and Dr. Ashutosh Biswas, Prof., Dept. of Medicine, AIIMS could not attend the meeting.

The Chairman welcomed the members of the Committee and apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE

University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under **category 'a'** and accordingly show cause notices have been issued to the concerned manufacturers.
2. FDCs requiring further deliberation with subject experts were categorized under **category 'b'** and further deliberations are in progress.
3. FDCs considered as rational by the Committee were categorized under **category 'c'** and accordingly approval letters have been issued to the concerned manufacturers.
4. FDCs requiring further generation of data were categorized under **category 'd'** and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee and have been found to be irrational. Based on the recommendations of the Committee, Show cause notices were served to the applicant firms as to why manufacturing license in respect of such FDCs may not be deemed to have been cancelled. Now, the firms have submitted their replies which need to be examined by the Committee.

The detailed therapeutic category-wise agenda containing FDCs related to Medicine category was placed before the Committee. The Committee also signed the No Conflict of Interest. The Committee discussed each FDC and made their recommendations as enclosed.

The Committee was apprised that Dr.Rita Sood, Prof.,Dept. of Medicine,AIIMS will not be able to attend the meeting on 07.01.2016.The Chairman of the Committee requested Dr.Richa Dewan to participate in the deliberations on 07.01.2016 as an expert member.

The meeting ended with the vote of thanks to the Chair.

(Dr. R.K. Khar) 6/1/16 (Dr. Bikash Medhi) 6/1/16 (Dr. C.D. Tripathi) 6/1/16

(Prof. Sanjay Singh) (Dr. Richa Dewan) 6/1/16 (Dr. C.L. Kaul) 6/1/16

6/1/16

(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 7.1.2016 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
3. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
4. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
5. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
6. Dr. C.L. Kaul, Former Director, NIPER - Member
7. Dr. Richa Dewan, Prof. & Head, Dept. of Medicine, MAMC, New Delhi
8. Dr. Rohit Saxena, Associate Prof.,Dept. of Opthalmolgy, AIIMS, New Delhi
9. Dr.R.K. Arya, Prof.& Head, Dept. of Orthopaedics, RML Hospital, New Delhi
10. Dr. Dipika Deka, Prof., Dept. of O&G, AIIMS, New Delhi
11. Dr. J.C. Passey, Prof. & Head, Dept. of ENT, MAMC, New Delhi

Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS could not attend the meeting.

The Chairman welcomed the members of the Committee and apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/83/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as irrational by the Committee were categorized under category 'a' and accordingly show cause notices have been issued to the concerned manufacturers.
2. FDCs requiring further deliberation with subject experts were categorized under category 'b' and further deliberations are in progress.
3. FDCs considered as rational by the Committee were categorized under category 'c' and accordingly approval letters have been issued to the concerned manufacturers.
4. FDCs requiring further generation of data were categorized under category 'd' and accordingly letters asking the firms to submit [illegible] have been issued to the concerned [illegible].

The members were [illegible] FDCs to be discussed in the meeting have already been examined by the [illegible] and have been found to be irrational. Based on the recommendations of the Committee, Show cause notices were served to the applicant [illegible] licence in respect of such FDCs may not be deemed [illegible]. Now, the firms have submitted their replies which need to be [illegible] by the Committee.

The [illegible] categories [illegible] containing FDCs related to 'Ophthalmology', 'Anaesthesia', 'Gynaecology', 'ENT', 'Cardiology' and '[illegible]' categories were placed before the Committee. The Committee also signed the No Conflict of Interest. The Committee discussed each FDC and made their recommendations as annexed. The Chairman requested Dr. R. Gupta, Professor in Medicine to attend meeting on 8.1.2016 as an Expert Member.

The meeting ended with the vote of thanks to the Chair.

[illegible]

(Dr. R.K. [illegible]) (Dr. [illegible]) (Dr. C.D. [illegible]) (Dr. Rohit [illegible])

(Prof. [illegible]) (Dr. [illegible]) (Dr. [illegible]) (Dr. [illegible])

(Dr. [illegible]) (Dr. J.C. [illegible])

(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 8.1.2016 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
3. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
4. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
5. Dr. C.L. Kaul, Former Director, NIPER - Member
6. Dr. Debashish, Prof., MAMC, New Delhi
7. Dr. Nihar Ranjan, Assoc. Prof., Dept. of Gastro , AIIMS, New Delhi
8. Dr. Viveka Jyotsana, Prof., Dept. of Endocrinology, AIIMS, New Delhi
9. Dr. B. Gupta, Prof. , General Medicine, HinduRao Hospital, NDMC, New Delhi

Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS, Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU and Dr. Ashutosh Biswas, Prof. AIIMs could not attend the meeting.

The Chairman welcomed the members of the Committee and apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under **category 'a'** and accordingly show cause notices have been issued to the concerned manufacturers.
2. FDCs requiring further deliberation with subject experts were categorized under **category 'b'** and further deliberations are in progress.
3. FDCs considered as rational by the Committee were categorized under **category 'c'** and accordingly approval letters have been issued to the concerned manufacturers.
4. FDCs requiring further generation of data were categorized under **category 'd'** and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee and have been found to be irrational. Based on the recommendations of the Committee, Show cause notices were served to the applicant firms as to why manufacturing license in respect of such FDCs may not be deemed to have been cancelled. Now, the firms have submitted their replies which need to be examined by the Committee.

The detailed therapeutic category-wise agenda containing FDCs related to **'CNS', 'Gastroenterology' and 'Endocrinology'** categories were placed before the Committee. The Committee also signed the No Conflict of Interest. The Committee discussed each FDC and made their recommendations as enclosed.

The meeting ended with the vote of thanks to the Chair.

(Dr. R.K. Khar) (Dr. Bikash Medhi) (Dr. C.D. Tripathi) 8/1/16 (Dr. B. Gupta) 8/1/16

(Dr. Debashish) (Dr. Nihar Ranjan) Dr. Viveka Jyotsana 8/1/16 (Dr. C.L. Kaul) 8/1/16.

(Prof. Chandrakant Kokate) 8/1/16.

Minutes of the Meeting of Expert Committee held on 9.1.2016 to review proposals and advice Drugs Controller General (India) in matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
3. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
4. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
5. Dr. C.L. Kaul, Former Director, NIPER - Member
6. Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS.
7. Dr. V. Ramesh, Prof., Dept. of Dermatology. Safdarjung Hospital, New Delhi
8. Dr. Hitendra Singh Tanwar, Ass. Prof., Dept. of Medicine, RML Hospital, New Delhi

Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU could not attend the meeting.

The Chairman welcomed the members of the Committee and apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

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In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under **category 'a'** and accordingly show cause notices have been issued to the concerned manufacturers.
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The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee and have been found to be irrational. Based on the recommendations of the Committee, Show cause notices were served to the applicant firms as to why manufacturing license in respect of such FDCs may not be deemed to have been cancelled. Now, the firms have submitted their replies which need to be examined by the Committee.

The detailed therapeutic category-wise agenda containing FDCs related to **'Dermatology'** categories were placed before the Committee. The Committee also signed the No Conflict of Interest. The Committee discussed each FDC and made their recommendations as enclosed.

The meeting ended with the vote of thanks to the Chair.

(Dr. R.K. Khar) (Dr. Bikash Medhi) (Dr. C.D. Tripathi) (Dr. Hitendera Singh Tanwar)

(Dr. C.L. Kaul) (Dr. Sanjiv Sinha) (Dr. V. Ramesh)

(Prof. Chandrakant Kokate)

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