

LIST OF APPROVED DRUG FROM 01-01-2011 to 31-12-2011

S.No	Name Of Drug	Indication	Date of issue
1.	Alpha Lipoic Acid USP 100mg + Methylcobalamin 1500mcg + Vitamin B6 IP 3mg + Folic Acid IP 1.5mg + Benfotiamine 50mg + Biotin USP 5mg + Chromium Picolinate USP Eq. to Chromium 200mcg Capsule	For the treatment of diabetic neuropathy	03.01.11
2.	Ropinirole ER Tablet 1 mg. (Additional Strength)	Same as approved	04.01.11
3.	Erlotinib HCl Tablet 150 mg (Additional Indication)	Monotherapy for the Maintenance Treatment of Patients with locally advanced metastatic non-small lung cancer whose disease has not progressed after four cycles of Platinum based First Line Chemotherapy.	04.01.11
4.	Moxifloxacin HCl BP 0.5% w/v + Bromfenac Sodium 0.09% w/v Eye drop	For the reduction of post operative inflammatory conditions of the eye	05.01.11
5.	Ferrous Ascorbate 100mg + Folic Acid IP 1.5mg + Cyanocobalamin IP 15mcg + Zinc Sulphate Monohydrate Eq. to Elemental Zinc 22.5mg Tablet	For the treatment of iron deficiency anaemia	05.01.11
6.	S (+) Etodolac 300mg +Thiocolchicoside 8mg Tablet	For the treatment of patients with acute painful musculoskeletal conditions	05.01.11
7.	Beclomethasone Dipropionate IP 100mcg + Formoterol Fumarate Dihydrate BP Eq. to Formoterol Fumarate 6 mcg Metered Dose Inhaler	For the treatment of bronchial asthma where use of inhaled corticosteroid therapy found appropriate	05.01.11
8.	Amlodipine Besilate IP Eq. to Amlodipine 5mg + Indapamide USP SR 1.5mg Tablet	For the treatment of mild to moderate hypertension	05.01.11
9.	Metformin HCl IP 500mg + Alpha Lipoic Acid USP 200mg Tablet	For the treatment of patients with diabetic polyneuropathy	05.01.11

10.	Spirolactone IP 25mg + Furosemide IP 40mg Tablet	Additional strength	05.01.11
11.	Bicalutamide Tablet 150 mg.(Additional Strength and Indication)	Indicated either alone or as adjuvant to radical Prostatotomy or radiotherapy in Patients with Locally advanced Prostate cancer at High risk for disease Progression.	05.01.11
12.	Paracetamol Chewable Tablet 500 mg. (Additional Dosage Form)	Same as approved	05.01.11
13.	Methylcobalamin 500mcg + Folic Acid IP 1.5mg + Zinc Sulphate IP 25mg + Chromium Polynicotinate 200mcg + Selenium as Sodium Selenite USP 65 mcg + Inositol 100mg + Alpha Lipoic Acid 50mg + Streptococcus faecalis 30 Millions (30 lakh) + Clostridium butyricum 2 Million (20 lakh) + Bacillus mesentericus 1 Million (10 lakh) + Lactic acid bacillus 50 Million (500lakh) Capsule	For Vitamins and Minerals deficiency states in adult patients	11.01.11
14.	Dextromethorphan Extended Release Oral Suspension 30 mg per 5 ml	For the Relief of Persistent Dry irritating cough in adult patients Only.	17.01.11
15.	Hydroquinone USP 2% w/w + Tretinoin USP 0.025% w/w + Allantoin USP 1%w/w Gel	For treatment of hyper pigmentry disorders	31.01.11
16.	Paracetamol Fast Release Tablet 500mg (Additional Dosage Form)	Same as approved	10.02.11
17.	Each bowel preparatory kit contains: One enteric coated tablet Biscodyl IP 5mg & One sachet of powder for reconstitution contains: Polyethylene glycol 3350NF: 210gm + Sodium Bicarbonate IP 2.86gm + Sodium Chloride IP 5.6gm + Potassium Chloride IP 0.74gm	For bowel cleansing prior to colonoscopy in adult patients only	11.02.11
18.	Ferric Carboxymaltose equivalent to elemental Iron...50mg/ml Injection	For the treatment of iron deficiency in adults when oral iron preparations are ineffective or cannot be used.	11.02.11

19.	Pidotimod Tablet 400 mg/800 mg & Oral Solution 400 mg/800 mg per 7ml	For infections of the respiratory system in secondary and primary immunodeficiency with alteration in maturation of T cells in adults only.	11.02.11
20.	Ursodeoxycholic Acid Suspension 125mg/5ml and 250 mg /5ml.	For the treatment of patients with chronic cholestatic liver disease.	11.02.11
21.	Iloperidone Tablets 1mg/2mg/4mg/6mg/8mg /10mg/12mg	For the acute treatment of adults with schizophrenia.	17.02.11
22.	Calf lung surfactant Intratracheal Suspension containing Phospholipids.... 35mg (containing 26 mg phosphatidylcholine of which 16mg is disaturated phosphatidylcholine) Proteins....0.65mg (including 0.26mg of surfactant associated proteins B) per ml	(a). As a prophylaxis therapy for premature infants <29 weeks of gestational age at significant risk for Respiratory Distress Syndrome (RDS). (b). For the treatment of infants <72 hours of age with RDS (confirmed by clinical and radiologic findings) and requiring endotracheal intubation.	17.02.11
23.	Baclofen ER Capsule 10 mg/50 mg. (Additional Strength)	Same as approved	17.02.11
24.	Dexketoprofen Trometamol ER Tablet 50 mg (Additional Strength)	Same as approved	21.02.11
25.	Gatifloxacin Eye drop 5 mg/ml	For the treatment of bacterial conjunctivitis caused by susceptible strains	21.02.11
26.	Paclitaxel Injection 30mg/100 mg/300 mg (additional Indication)	Advanced squamous cell carcinoma of Head and Neck SCCHN: 1. Diagnosed but unrectable locally advanced SCCHN 2. Recurrent SCCHN, if surgery or radiation is not feasible. 3. Palliative treatment of metastatic SCCHN.	24.02.11
27.	Eslicarbazepine Acetate Tablets 200mg/400mg/600mg/800mg	As an adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation.	07.03.11

28.	Ketoprofen Plaster (Size - 7cm x 10 cm)	For the Relief of Musculoskeletal pain and Inflammation.	09.03.11
29.	Meropenem IP 1000mg + Sulbactam sodium USP 500mg injection	For the treatment of lower respiratory tract infection caused by gram negative bacteria in adults only	15.03.11
30.	Dasatinib 20mg/50mg/70mg (Additional Indication)	Treatment of newly Diagnosed Adults with Chronic Myeloid Leukaemia (CML) in Chronic Phase.	16.03.11
31.	Adenosylcobalamin 15mcg + Ferrous Ascorbate 100mg + Folic Acid IP 1.5mg + Zinc Sulphate USP Eq. to Elemental Zinc 22.5mg tablet	For the treatment of iron deficiency anaemia in adults only	21.03.11
32.	Tioconazole Vaginal Gel 65mg per gm	For the local treatment of vulvo vaginal candidiasis in adult patients.	22.03.11
33.	Aspirin (EC Tablets) 75mg/75mg/150mg +Rosuvastatin (Granules) 5mg/10mg/10mg Capsules	For the treatment of dyslipidemia associated with arthersclerotic arterial disease with risk of Myocardial infarction, stroke or peripheral vascular disease.	30.03.11
34.	Ilaprazole Tablets 5mg/10mg	For the treatment of duodenal ulcer in adults only.	05.04.11
35.	Rosuvastatin Calcium Tablets 5/10/20mg (Additional Indication)	1. As adjunct to diet to reduce Total-C, LDL-C, and ApoB levels in adolesent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDL-C> 190mg/dL or > 160mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors. 2. As an adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia).	05/04/2011
36.	Quetiapen fumarate Sustained Release Tablets 50mg and 100mg (Additional Strength)	Same as approved	05/04/2011
37.	Esomeprazole magnesium Delayed Release Tablets 20mg/40mg (Additional Indication)	1. Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Ulcer. 2. Risk Reduction of NSAID Associated Gastric Ulcer. 3. Prolonged Treatment after IV Induced	06/04/2011

		Prevention of Rebleeding of Peptic Ulcer.	
38.	Asenapine Maleate Sublingual Tablets 5mg/10mg	For acute treatment of schizophrenia in adults only.	07.04.11
39.	Cefpodoxime IP 100mg/100mg/200mg/200mg +Ofloxacin IP 100mg/200mg/100mg/200mg Tablets	For the Treatment of Lower and upper respiratory tract infection and Typhoid fever in adults only	16.04.11
40.	Tapentadol Hydrochloride Tablets 50mg/75mg/100mg	For relief of moderate to severe acute pain in adults 18 years of age or older.	18.04.11
41.	Cefixime Trihydrate IP Eq. to Anhydrous Cefixime 100mg/200mg + Ofloxacin IP 100mg/200mg Dispersible Tablet (Additional dosage form)	Same as approved	20.04.11
42.	Atorvastatin calcium 5mg/10mg/20mg/40mg/80mg (Additional Dosage Form)	1) As an Adjunct to Diet to Reduce Elevated Total Cholesterol and Triglyceride Levels in Patients with Primary HyperCholesterolemia and Mixed Dyalipidemia (Type IIa and IIIb). 2) In adult patients with type II diabetes and without clinically evident coronary heart disease to reduce the risk of myocardial infarction and stroke. 3) To reduce the risk of stroke in adult patients without clinically evident coronary heart disease but multiple risk factors for coronary heart disease	20/04/2011
43.	Fluvestrant 250mg/5ml Injection(Additional Dosage Regime)	(Same as approved) Posology : Adult females (Including the elderly). The recommended dose is 500mg at interval of one month, with an additional 500mg dose given two weeks after initial dose.	20/04/2011
44.	S-Bupivacaine Hydrochloride Injection 2.5mg/5mg/7.5mg per ml	For surgical anaesthesia in adults for epidural (including caesarean section), intrathecal, peripheral nerve block.	28.04.11
45.	Dexketoprofen 50mg + Dicyclomine 20mg per 2ml Injection	For the treatment of acute colicky pain in adult patients	28.04.11

46.	Lacosamide Syrup 15mg/ml (Additional Dosage Form)	Same as approved	02/05/2011
47.	Primaquine Tablet 45mg (Additional Strength)	Used as Gametocytocidal drug in P. falciparum infections to prevent transmission of falciparum malaria particularly in area where there is potential for re-introduction of malaria.	05/05/2011
48.	Hyaluronic Acid Pre-filled Syringe 30mg/2ml & 60mg/4ml (Additional Strength)	To Restore Visco-Elastic Properties of the Synovial Fluid, with Alleviation of Pain and improvement of Joint, Mobility in Patients Affected by Degenerative or Mechanical Arthropathy.	05/05/2011
49.	Levocetirizine Di-HCl Syrup 2.5mg/5ml (Additional Indication)	For the Treatment of Allergic Rhinitis and Chronic Urticaria in Children from 6 months of Age.	05/05/2011
50.	Ivabradine Tablets 5mg/7.5mg (Additional Indication)	For Symptomatic Treatment of Chronic Stable Angina Pectoris in Coronary Artery Disease Patients with Normal Sinus Rhythm, Indicated in Combination with Beta-Blockers in Patients Inadequately Controlled with an Optimal Beta-Blocker Dose and Whose Heart rate is >60bpm.	05/05/2011
51.	Sunitinib malate Capsules 12.5mg/25mg (Additional Indication)	Treatment of Unresectable or Metastatic Well-differentiated Pancreatic Neuroendocrine Tumours with Disease Progression in Adults	05/05/2011
52.	Levetiracetam Oral Solution 100mg/ml (Additional Indication)	As Adjunctive Therapy in the Treatment of Partial Onset Seizures With or Without Secondary Generalisation in Adults, Children and Infants from 1 Month of Age with Epilepsy.	05/05/2011
53.	Esomeprazole Delayed Release Granules for Oral Suspension: Each 1g sachet contains: Esomeprazole Magnesium I.P. (as trihydrate) equivalent to Esomeprazole 10 mg as enteric coated granules (Additional Dosage Form)	1) Treatment of Gastroesophageal Reflux Disease (GERD). 2) Risk Reduction of NSAID Associated Gastric Ulcer. 3) H. Pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence. 4) Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome.	13/05/2011

54.	Bendamustine Hydrochloride Injection 100mg/vial (Additional Indication)	For the use in Indolent B-cell Non-Hodgkin's Lymphoma (NHL) that has Progressed During or Within Six months of Treatment with Rituximab or a Rituximab containing Regimen.	18/05/2011
55.	Gatifloxacin 0.3% + Loteprednol Etabonate 0.5% + Benzalkonium Chloride 0.01% w/v Ophthalmic suspension	For Post-Operative Steroid repulsive inflammatory Ocular conditions when Ocular bacterial infections or a risk of bacterial infection exists	19.05.11
56.	Diclofenac Colestyramine 145.6 mg corresponding to 75mg Diclofenac Sodium Capsules.	For the treatment of acute arthritis (including attacks of gout), chronic arthritis especially rheumatoid arthritis (chronic polyarthritis), ankylosing spondylitis (Morbus Bechterew) and other inflammatory, rheumatoid syndromes of vertebral column.	19.05.11
57.	Meropenem Injection IP 500mg/1.0g (Additional Indication)	For Treatment, in Children, of the following Infections Caused by Single or Multiple Bacteria Sensitive to Meropenem: Pneumonias and Nosocomial Pneumonias, Urinary Tract Infections, Intra-abdominal Infections, Gynaecological Infections Such as Endometriatis and Pelvic Inflammatory Disease, Skin and Skin Structure Infections, Meningitis, Septicaemia. Meropenem has been Proved Efficacious alone or in Combination with other Antimicrobial agents in the Treatment of Polymicrobial Infections.	20/05/2011
58.	Brinzolamide Ophthalmic Suspension 1% w/v	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.	26.05.11
59.	Besifloxacin Ophthalmic Suspension 0.6% w/v	For the treatment of bacterial conjunctivitis.	31.05.11
60.	Diclofenac (as EC Tablets) 25mg + Paracetamol 325 mg Capsule (Additional Strength)	Same as approved	31.05.11

61.	Amlodipine 10mg/10mg+ Telmisartan 40mg/80mg Tablets (Additional Strength)	Same as approved	31.05.11
62.	Latanoprost 50mcg/ml Ophthalmic Solution (Additional Indication)	For the Reduction of Elevated Intraocular Pressure in Paediatric Patients with Elevated Intraocular Pressure and Paediatric Glaucoma.	02/06/2011
63.	Botulinum toxin type A 50 Units/Vial and 100 Units/Vial (Additional Indication)	For the prophylaxis of headaches in adults with chronic migraine	02/06/2011
64.	Clostridium Botulinum Toxin Type-A Injection 100Units/Vial (Additional Indication)	For focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy	03/06/2011
65.	Donepezil Sustained Release Tablet 23mg (Modified Dosage Form)	For the Treatment of Mild to Moderate Severe Alzheimer's Dementia.	03/06/2011
66.	Rifaximin Oral Suspension 100mg/5ml (New Dosage Form)	Treatment of Infectious Diarrhoea in Adult and Children(>2years of age and above).	09/06/2011
67.	<p>1. PROBIO :</p> <p>Each sachet (1g) contains:</p> <p>Total Probiotic.... Not less than 1.25 Billion CFU (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, Saccharomyces boulardii)</p> <p>2. PROBIO & PREBIO (F)s</p> <p>Each sachet (1g) contains:</p> <p>Probio (CMP 5) Total Probiotic...Not less than 1.25 Billion CFU (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, Saccharomyces boulardii) Fructo Oligo Saccharides 100mg</p>	For the treatment of rotavirus diarrhoea.	09.06.11

	<p>3. PROBIO & PREBIO (D)</p> <p>Each sachet (1.3g) contains:</p> <p>Probio (CMP 5) Total probiotic... not less than 1.25 billion CFU (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, Saccharomyces boulardii) Fructo Oligo Saccharides...1000mg</p>		
68.	Paracetamol 325mg + Tramadol Hydrochloride 37.5 mg Tablets	Additional indication. (For Symptomatic Treatment of Moderate To Severe Pain.)	21.06.11
69.	Silodosin Capsules 2mg/4mg/8mg	For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adults only.	23.06.11
70.	Tiapride Hydrochloride Tablets 25mg/50mg/100mg	For the treatment of agitation and aggressiveness in adult patients with cognitive impairment.	23.06.11
71.	Eperisone Hydrochloride Sustained Release Capsule 75mg/150mg (Modified Dosage Form)	For Improvement of Myotonic Conditions caused by Neck-Shoulder Arm Syndrome, Scapulohumeral Periarthritis and Low Back Pain.	24/06/2011
72.	Fexofenadine 120mg + Montelukast 10mg Chewable tablet	Additional dosage form	07.07.11
73.	Each Combipack of 21 tablets contains : A) FDC of Norgestrel & Ethinyl estradiol tablets IP Each sugar coated white tablet contains: Norgestrel 0.30mg & Ethinyl estradiol 0.03mg B) 7 tablets of Ferrous Fumarate: Each sugar coated tablet contains : - Ferrous Fumarate 75mg eq. to 24.375mg of ferrous iron	As contraceptive pill for women	27.07.11
74.	Cefixime (SR) 400mg +Moxifloxacin (SR) 400 mg Tablets	For the treatment of lower respiratory tract infections in adults only	08.08.11
75.	Alpha Lipoic acid 100mg + Folic acid 1.5mg + Methylcobalamin 1500mcg + Pyridoxine Hydrochloride 3mg + Vitamin D3 1000 IU Tablets	For the treatment of Diabetic neuropathy	10.08.11

76.	Ranolazine ER Tablet 375mg/750mg (Additional Strength)	Same as approved	11/08/2011
77.	Gadobenate dimeglumine IV Injection (Gadobenate dimuglimine 529mg equivalent to Gadobenate acid 334mg + Meglumine 195 mg) (Additional Indication)	Contrast-enhanced MR-angiography where it improves the diagnostic accuracy for detecting clinically significant steno-occlusive vascular disease in patients with suspected or known vascular disease of the abdominal or peripheral arteries.	11/08/2011
78.	Tacrolimus Capsules 0.5mg/1mg/5mg (Additional Indication)	Lupus nephritis(in a case where the effect of steroids is insufficient or administration of steroids is difficult because of their adverse reactions)	11/08/2011
79.	Imatinib mesylate 100 mg/400mg Tablets and 100mg Capsules (Additional Indication)	1. For the Treatment of Adult Patients with newly Diagnosed Philadelphia Chromosome Positive Acute Lymphoblastic Leukaemia(Ph+ALL) integrated with chemotherapy 2. Treatment of Adult patients with relapsed or refractory Ph+ALL as monotherapy 3. Treatment of Adult patients with Myelodysplastic/Myeloproliferative diseases (MDS/MPD) associated with platelet - derived growth factor receptor (PDGFR) gene rearrangements. 4. Treatment of Adult Patients with Systemic Mastocytosis (SM) without the D816V c-Kit mutation or with c-Kit mutational status unknown 5. Treatment of Adult Patients with Hypereosinophilic Syndrome(HES) and/or Chronic Eosinophilic Leukaemia(CEL) 6. Treatment of Adult Patients with Unrespectable, Recurrent and/or Metastatic Dermatofibrosarcoma Protuberans (DFSP)	11/08/2011
80.	Rifaximin Tablet 550 mg (Additional strength and Additional Indication)	For Reduction in Risk of Overt Hepatic Encephalopathy (HE) Recurrence in Patients \geq 18 years of Age.	18/08/2011
81.	Levosulpride (SR) 75mg + Rabeprazole sodium IP (EC Pellets) 20mg Capsule	For the treatment of Gastro-oesophageal Reflux Disease (GERD)	19.08.11
82.	Each Combikit contains Part A - One film coated tablet of Tenofovir Disoproxil Fumarate 300mg eq. to Tenofovir 245mg + Emtricitabine 200mg. Part B - One film coated tablet of Atazanavir sulphate eq. to Atazanavir 300mg + Ritonavir 100mg	For the treatment of HIV infection in adults.	23.08.11

83.	Diclofenac sodium (SR) 100mg + Eperisone Hydrochloride (SR) 150mg Capsules	For the treatment of patient with acute musculoskeletal spasm associated with low back pain.	24.08.11
84.	Rosuvastatin Calcium eq. to Rosuvastatin 20mg/20mg + Fenofibrate BP 67.5mg/145mg Tablets	Additional Strength	24.08.11
85.	Eletriptan Hydrobromide Tablets 20mg/40mg	For the treatments of Migraine with or without aura in adults	25.08.11
86.	Acyclovir 50g + Hydrocortisone 10mg Cream	For the early treatment of recurrent cold sores in adult patients to reduce likelihood of ulcerative cold sores and to shorten the lesion healing time	30.08.11
87.	Clindamycin Phosphate eq. to Clindamycin 1% w/w + Hydrous Benzoyl Peroxide eq. to Anhydrous Benzoyl peroxide 2.5% w/w topical gel	For topical treatment of inflammatory acne vulgaris (Additional lower strength)	30.08.11
88.	Polyethylene glycol 0.4% w/v + Propylene Glycol 0.3% w/v Eye Drops	For temporary relief of burning and irritation due to dryness of the eye	13.09.11
89.	Glutathione for Injection 600mg	For the treatment of alcoholic liver diseases like alcoholic fatty liver, alcoholic liver fibrosis, alcoholic liver cirrhosis, and hepatitis	14.09.11
90.	Udenafil Tablet 100mg/200mg	For the treatment of erectile dysfunction	15.09.11
91.	Metformin (ER)1000mg/500mg +Saxagliptin 2.5 mg/5mg Tablets	As an Adjunct to diet and exercise to improve glycemic control in adults patients with type 2 diabetes mellitus when treatment with both Saxagliptin and Metformin is appropriate	19.09.11
92.	Ceftriaxone Sodium eq. to Ceftriaxone Sodium 1000mg/2000mg + Sulbactam Sodium eq. Sulbactam 500mg/1000mg.injection	Additional Indication - For the treatment of urinary tract infections and lower respiratory tract infections, various bacteria	21.09.11
93.	Difluprednate 0.05% w/v + Moxifloxacin 0.5% w/v Eye Drops	For steroid responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists	22.09.11
94.	S(-) Amlodipine 2.5mg/5mg + Clopidogrel 75mg/75mg Tablets	For the treatment of high risk hypertensives who need anti-platelet therapy especially for prophylaxis of artherothrombotic events in patients	22.09.11

		with a history of recent stroke or established peripheral arterial disease	
95.	Acrivastine Capsules 8mg	For the symptomatic relief of allergic rhinitis.	26.09.11
96.	Tacalcitol ointment 4mcg	For the treatment of psoriasis vulgaris in adults only.	26.09.11
97.	Each Combipack contains: - A) One tablet of Risedronate Sodium - Each film coated tablet contains: Risedronate Sodium (as Risedronate Sodium Hemi-Pentahydrate) - 35 mg B) Six Capsules of FDC of Calcitriol + Calcium carbonate + Zinc Each soft gelatin capsule contains : - Calcitriol IP - 0.25mcg Calcium Carbonate IP - 500mg (eq. to elemental calcium 200mg) Zinc (as Zinc Sulphate USP) 7.5 mg	For the treatment of Osteoporosis in post menopausal women	30.09.11
98.	Akiskiren Hemifumarate eq. to Aliskiren 150mg/150mg/300mg/300mg + Amlodipine Besilate IP eq. to Amlodipine 5mg/10mg/5mg/10mg Tablets	For the treatment of hypertension: a) As initial therapy in the patient likely to need multiple drugs to achieve blood pressure control. B) In the patients whose blood pressure is not adequately controlled with the Aliskiren alone or Amlodipine (or another di-hydropyridine calcium channel blocker) alone. C) As replacement therapy in patients already receiving Aliskiren and Amlodipine from separate tablets at the same dose level.	12.10.11
99.	Ferrous Ascorbate eq. to elemental iron 100mg + Folic acid IP 1.1mg + Methylcobalamin 1.5mg + Zinc Sulphate monohydrate IP eq to elemental Zinc 22.5mg Tablets. (Additional strength)	For the treatment of Iron deficiency anaemia	19.10.11
100.	Arterolane Maleate 150mg + Piperaquine Phosphate 750mg Tablet	Treatment of acute uncomplicated malaria infection due to Plasmodium falciparum in adults.	19.10.11

101.	Tafluprost Eye Drops 0.0015% w/v	For the reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension.	21.10.11
102.	Gatifloxacin IP eq. to Gatifloxacin (Anhydrous) 3.0mg + Difluprednate 0.5mg + Benzalkonium Chloride IP (As preservative) 0.01% w/v Eye Drops	For the treatment in the patients with inflammatory ocular conditions where bacterial infection or a risk of bacterial ocular infection exists	24.10.11
103.	Alprazolam sublingual tablets 0.5mg/1mg (New dosage form)	in the treatment of anxiety associated with depression and for the treatment of panic disorder	27/10/2011
104.	Gemcitabine Hydrochloride for injection 2g/vial (New dosage form)	In the management of non small cell lung cancer	27/10/2011
105.	Diazinon Flea Drops Spot on Dogs 30.0% w/w	For dogs infected with fleas.	11.11.11
106.	Diclofenac Sodium IP (as sustained release Pellets) 100mg + Thiocolchicoside (as sustained release pellets) 16mg Capsule. (New Dosage Form)	For the treatment of acute inflammation conditions associated with spasm in adults only.	15.11.11
107.	Imatinib mesylate 100 mg/400mg Tablets (Additional Indication)	1. Adjuvant treatment of adult patients following resection of gastro- intestinal stromal tumours (GIST) 2. For the treatment of CML in blast crisis, accelerated phase or in chronic phase after failure of interferon alpha therapy. 3. Newly diagnosed Philadelphia positive chronic myeloid leukaemia (Ph+CML)	15/11/2011
108.	Epalrestat 50mg + Methylcobalamin 500mcg Tablets	For the treatment of Diabetic Neuropathy	16.11.11
109.	Cabazitaxel Injection 60mg / 1.5ml	In combination with prednisone for treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.	16.11.11
110.	Ketorolac Tromethamine IP 4.00mg + Olopatadine Hcl eq. to Olopatadine 1.00mg + Benzalkonium Chloride IP 0.05mg	For the treatment of seasonal allergic conjunctivitis in adults only	21.11.11

	Ophthalmic solution		
111.	Tramadol Hcl IP (As Immediate Release Layer) 50mg + Diclofenac Sodium IP (As Sustained Release Layer) 75mg Tablets	For the symptomatic treatment of moderate to severe pain in adult patients	21.11.11
112.	Budesonide IP 1mg/0.5mg + Formoterol Fumarate Dihydrate IP eq to Formoterol Fumarate 20mcg/20mcg Respirator suspension. (Additional Strength)	For the treatment of asthma where the use of corticosteroid and long acting beta agonist in combination is appropriate	21.11.11
113.	Ondansetron Fast Dissolving Strips 4mg/8mg (New dosage form)	1) for chemotherapy induced nausea and vomiting. 2)for post-operative nausea and vomiting	22/11/2011
114.	Amlodipine Besilate IP eq.to Amlodipine 10mg/5mg/5mg/5mg/2.5mg + Olmesartan Medoxomil 40mg/40mg/20mg/5mg/5mg + Hydrochlorothiazide IP 25mg/12.5mg/12.5mg/12.5mg/12.5mg Tablet	For the treatment of essential hypertension	23.11.11
115.	Each Combipack contains Part (A) One Strip of FDC of Ramipril + Amlodipine Tablets;- Each uncoated tablet contains Ramipril IP - 5mg, Amlodipine besylate IP eq to Amlodipine 5mg B) Each Film coated tablet contains ;- Atorvastatin Calcium IP eq to Atorvastatin 10mg/20mg.	For the treatment of hypertension and as an adjunct to diet in patients to reduce elevated total cholesterol and triglyceride levels hypertension and dyslipidemia. The polypack should be used in patients for whom treatment with all of the three i.e Ramipril, Amlodipine and Atorvastatin is appropriate.	28.11.11
116.	Topotecan Hydrochloride capsules 0.25/1mg (New dosage form)	same as approved	28/11/2011
117.	Albendazole tablet 400mg and suspension 400mg/10ml (Additional Indication)	For the treatment of systemic helminth infections 1. Neurocysticercosis 2. Echinococcosis	28/11/2011
118.	Fluconazole tablet 300mg (Additional strength)	same as approved	28/11/2011

119.	Rosuvastatin Calcium IP eq to Rosuvastatin 5mg + Ezetimibe 10mg. (Additional Strength)	For the treatment of patients with primary hypercholesterolemia.	05.12.11
120.	Iopromide injection (Equ. To 300 & 370mg of Iodine) (Additional Indication)	for intravascular use and use in body cavities for contrast enhancement in computerised tomography (CT), Arteriography and Venography, Intravenous /Intraarterial digital subtraction angiography(DSA); Intravenous urography, use of ERCP, Arthrography and Examination of other body cavities.	05/12/2011
121.	Micafungin sodium for Injection 10mg per vial/50mg per vial (Additional Indication)	1) Prophylaxis of Aspergillus Infections in Patients Undergoing Hematopoietic Stem Cell Transplantation. 2) Treatment of Patients with Fungemia, Respiratory mucosis, Gastrointestinal mycosis caused by Aspergillus sp.	05/12/2011
122.	Tolperisone Hcl IP 150mg + Diclofenac IP 50mg Tablets	For the treatment of Patients with acute muscle/musculoskeletal spasm in adult	07.12.11
123.	Paracetamol IP 325mg + Pamabrom USP 25mg Tablets	For the treatment of patient with pre-menstrual syndrome in adults only	07.12.11
124.	Dosulepine Hcl 50mg/75mg + Methylcobalamin 1500mcg/1500mcg Tablets	For the treatment of neuropathic pain.	08.12.11
125.	Trifluridine Eye Drops 1% w/v	For the treatment of primary keratoconjunctivitis and recurrent epithelial keratitis due to herpes simplex viruses type 1 and 2.	08.12.11
126.	Dabigatran Etxilate(as Mesilate) hard gelatin Capsules 75mg/110mg/150mg	For prevention of stroke, systemic embolism and reduction of vascular mortality in adult patients with atrial fibrillation.	12.12.11
127.	Cefuroxime Sodium 250mg intramammary infusion for Veterinary (PFS) (New dosage form)	For the treatment of Clinical mastitis in milking cows	13/12/2011
128.	Montelukast Sodium IP eq.to Montelukast 10mg +Olopatadine Hcl 5mg Tablets	For the treatment of relief of symptoms of allergic rhinitis	16.12.11

129.	Fosaprepitant (as Dimeglumine) for Injection 150mg.	1. Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin based cancer chemotherapy in adults. 2. Prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy in adults.	16.12.11
130.	Abiraterone Acetate Tablets 250mg	In combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel.	16.12.11
131.	Crizotinib hard gelatin Capsules 200mg/250mg	For the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK) – positive as detected by an FDA-approved test.	16.12.11
132.	Luliconazole lotion 1 % W/V (new Dosage Form)	Same as approved.	19-12-11
133.	Etizolam CR Tablets 1.5 mg/3 mg (modified Dosage Form)	Same as approved.	19-12-2011
134.	Amlodipine Besilate IP eq. to Amlodipine 5mg + Perindopril Erbumine BP 8mg Tablets. (Additional Strength).	For the treatment of mild to moderate hypertension in adults only and or treatment of stable coronary artery disease in patients already controlled with Perindopril & Amlodipine given concurrently at same dose level	20.12.11
135.	Posaconazole oral suspension 40 mg/ ml (additional Indication)	Zygomycosis in patients with disease refractory to other therapy, or patients who are intolerant of other therapy.	20-12-2011
136.	Everolimus Tablet 5 mg/10 mg (additional Indication)	Indication for the treatment of progressive neuroendocrine tumours of pancreatic origin (PNET) in patient with unresectable, locally advanced or metastatic disease.	21-12-2011
137.	Iron Amino Acid Chelate as Ferrous Bisglycinate (75mg) eq. to Elemental Iron 15mg + Folic acid IP 0.25mg + Vitamin B 12 IP 3.75mcg +Zinc Picolinate (26mg) eq. to	For the treatment of Iron Deficiency Anaemia	22.12.11

	Elemental Zinc 5.5mg Syrup		
138.	Piroxicam Sublingual Tablet 20 mg (Additional Dosage Form)	In the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, cervical spondylitis and other Musculoskeletal disorder.	27-12-2011
139.	Zoledronic Acid 4 mg/100 ml ready to use (RTU) solution for I.V Infusion (Additional Dosage Form)	Treatment of: 1. Hypercalcemia of malignancy. 2. Patient with myeloma and patients with documented bone metastases from solid tumours, in conjunction with standard antineoplastic therapy.	27-12-2011
140.	Everolimus Tablet 5 mg/10 mg (additional Indication)	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis.	27-12-2011