

LIST OF APPROVED DRUG FROM 01-01-2013 to 31-12-2013

S.No	Name Of Drug	Indication	Date of issue
1.	Diclofenac Diethylamine BP 2.32 % w/v Eq to Diclofenac Sodium 2.00 % w/v + Methyl Salicylate IP 10.00% w/v + Menthol 5.00 % w/v + Absolute Alcohol IP 10.00 % v/v Topical Solution (Additional Strength)	For the Treatment of Acute Lower Back Pain	01.01.2013
2.	Telmisartan 20mg + Amlodipine Besylate Eq. to Amlodipine 2.5mg + Hydrochlorothizide 6.25mg Tablets (Additional Strength)	For the Treatment of Essential Hypertension	03.01.2013
3.	Amlodipine besilate IP Eq. to Amlodipine 10mg + Indapamide SR 1.5 mg Tablet (Additional Strength)	For the treatment of mild to moderate Hypertension	02.01.2013
4.	Nicoumalone Tablets 0.5mg/5mg/6mg	For the prevention and treatment of thromboembolic diseases such as venous thrombosis, atrial fibrillation with embolization, pulmonary embolism and as an adjunct in the treatment of coronary occlusion.	18.1.13
5.	Ruxolitinib Tablet 5mg/15mg/20mg	For the treatment of patients with myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis.	28.01.2013
6.	DabigatranEtexilateMesilateeq to DabigatranEtexilate 75mg/110mg/150mg	For the prevention of venous thromboembolic events in patients who have undergone orthopaedic surgery	11.2.13
7.	Dexamethasone Intravitreal Implant 0.7mg (in solid polymer drug delivery system)	For the treatment of non-infectious uveitis affecting the posterior segment of the eye. However it should not be used when there is gap in posterior capsule.	20.2.13
8.	Cefixime Tablets 200mg & Cefixime Oral Suspension 100mg/5ml	For the treatment of enteric (typhoid) fever.	22.2.13
9.	Diclofenac Colestyramine 145.6mg Capsule Corresponding to Diclofenac Sodium 75mg (Additional Indication)	For the treatment of post-traumatic or post-operative swelling and inflammation	25.2.13

10.	Saroglitazar 2mg/4mg Tablets	For the treatment of diabetic dyslipidemia and hypertriglyceridemia with type-2 diabetes mellitus not controlled by statin therapy	25.2.13
11.	Tadalafil Tablet 2.5mg/5mg	1.For the treatment of erectile dysfunction. 2. For the treatment of erectile dysfunction with benign prostatic hyperplasia.	27.2.13
12.	Azithromycin Tablet 250mg/500mg	For the treatment in uncomplicated multidrug resistant enteric fever only	6.3.13
13.	BetahistineDihydrochloride SR Tablets 24mg/32mg/48mg	For the symptomatic treatment of peripheral vertigo	14.3.13
14.	Palonosetron Melt in Mouth Tablets 0.5mg	For prevention of chemotherapy induced nausea and vomiting	19.3.13
15.	Iobitridol Solution for Injection Each 100mg solution contain 65.81 g Iobitridolcorresponding mass of Iodine 30gm	By intracavity route for Arthrography and Hysterosalpingography.	19.3.13
16.	Everolimus 2.5mg/5mg/10mg Tablets	1. For the treatment of tuberous sclerosis complex (TSC) who have renal angiomyolipoma not requiring immediate surgery. 2. For the treatment of postmenopausal women with hormone receptor positive advanced breast cancer in combination with an aromatase inhibitor.	21.3.13
17.	Each sustained release tablet contains: Thiocolchicoside IP 8/16mg + Lornoxicam 8/16mg (Additional Strength)	For the treatment of patients with acute painful musculoskeletal conditions	08.04.2013
18.	Combination of Lactic Acid Bacteria (VSL#3) Sachet	For mild to moderately active ulcerative colitis as an adjunctive therapy subject to condition that it should not be used in patients who are on steroids or immunocompromised.	8.4.13
19.	Tolperisone HCl 450mg + Diclofenac Sodium IP100mg SR tablets (Additional Strength)	For the treatment of Patients with acute muscle/musculo skeletal spasm in adult	12.04.2013

20.	Telmisartan IP 80mg + Hydrochlorothiazide IP 25mg uncoated bilayered tablet (Additional Strength)	For the treatment of hypertension as second line therapy	14.05.2013
21.	Carboxy Methyl Cellulose Sodium Lubricant Eye Drops 0.5% w/v (Unit dose pack without preservative)	For temporary relief from burning irritation and discomfort due to dryness of the eye or due to exposure to wind or sun. May also be used as a protectant against further irritation.	27.5.13
22.	Garenoxacin Mesylate tablets 200mg	For the treatment of bacterial respiratory tract infection	07.06.13
23.	Trimethoxysilyl Quaternary Ammonium Chloride 0.40% hand protectant and sanitizer	Hand Protectant and Sanitizer for external use. Effective upto 24 hours.	11.06.13
24.	Sildenafil Citrate Orally Disintegrating Strips. 25mg/50mg (Additional Dosage Form)	For the treatment of erectile dysfunction.	05.07.2013
25.	Dextromethorphan Hydrobromide Extended Release suspension 30mg/5ml (Additional Dosage Form)	For the relief of persistent dry irritating cough in adults patients only.	01.08.2013.
26.	Iron (III) isomaltoside 1000 solution for injection/infusion 100mg per ml	For the treatment of iron deficiency anaemia when oral iron preparations are ineffective or cannot be used and when there is a clinical need to deliver iron rapidly.	20.08.13
27.	Tramadol HCL 200mg Controlled Release tablet (Additional Dosage Form)	For use in in-patients under hospital settings for severe acute pain for a period not exceeding 5 days.	12.09.13
28.	FDC of Aeterolane Malate (150mg) + Piperaquine Phosphate (750mg) Tablet	Treatment of acute uncomplicated malaria infection due to Plasmodium vivax in adults	11.10.2013
29.	Micronised Purified Flavonoid Fraction of Rutacea 1000 mg (MPFF) Each film coated tablet contains "Diosmin 900mg and Flavonoids expressed as Hesperidine 100mg of Micronised Purified Flavonoid Fraction of	Acute hemorrhoid piles.	28.11.13

	Rutaceae 1000mg (MPFF) (Additional strength)		
30.	Artesunate injection. Each combipack contains: "Artesunate for injection 120mg (Each vial contains Artesunate IP 120mg), Sodium bicarbonate injection IP 5%w/v (Each 2ml ampoule contains: Sodium Bicarbonate IP 5% w/v), Sodium chloride Injection IP 0.9% w/v (Each 10ml ampoule contains: Sodium chloride IP 0.9% w/v)" (Additional strength)	Promoted for use in severe malaria including cerebral malaria and as a second line in chloroquine resistant malaria cases only.	13.11.13
31.	Tapentadol Extended release Tablet 50mg (Additional Strength)	For use in in-patients for dose titration under hospital settings for severe acute pain for a period not exceeding 5 days.	12.11.13
32.	Divalproex Sodium Oral Solution 500mg/5ml (Additional Dosage Form)	For monotherapy and adjunctive therapy in the treatment of patients with complex partial seizures that occur either in isolation or in association with types of seizures for adult patients only.	23.12.13
33.	Diclofenac Sodium Sustained Release Tablet (Two layered tablets) 150mg. Each tablet contains Diclofenac Sodium IP-125 mg Slow Release, Diclofenac Sodium IP-25 mg Immediate Release(Additional Dosage Form)	For symptomatic treatment of pain and inflammation in irritation in association with degenerative joint disease/osteoarthritis.	20.12.13
34.	Ivabradine HCL Tablets 5mg/7.5mg (Additional indication)	Additional indication of "treatment of chronic heart failure in chronic heart failure NYHA II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is > 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated".	19.12.13

35.	Risperidone prolonged release suspension for injection (Deep Intramuscular Deltoid route using appropriate safety needle) (Additional route of administration)	Same as already approved	19.12.13
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