

List of Drugs approved

List of Drugs approved during 2006 to 2021

Sl. No.	Name of Drug	Pharmacological Classification	Date of Approval
1.	Oxandrolone Tablet (2.5/10 mg)	To promote weight gain	4-8-06
2.	Tenofovir Disoproxil Fumarate 300 mg + Emtricitabin 200 mg + Efavirenz 600 mg tablet	For HIV-1 infection	1-8-06
3.	Lumiracoxib Tablet (100/200/400 mg)	For OA, RA acute pain & primary dysmenorrhoea	1-8-06
4.	Quetiapine S.R tablet 200/300 mg	For psychotic disorder	1-8-06
5.	Amisulpiride Tablet (50/100/200 mg)	For schizophrenic disorder	1-8-06
6.	Baclofen E.R capsule (30 mg)	For spasticity	1-8-06
7.	Forskolin Eye drop (1%)	For open angle glaucoma	27-7-06
8.	Sodium Hyaluronate Injection (1%)	For OA	26-7-06
9.	Clobetasol Propionate (0.05%) + Calcipotriol Ointment (0.005%).	For plaque psoriasis	20-7-06
10.	ISMN SR 30 mg + Aspirin 75/150 mg tablet (additional strength).	Same as approved	20-7-06
11.	Cefixime 200 mg + Pot. Clavulanate (125 mg) tablet	Antibiotic	20-7-06
12.	Levocetirizine 2.5/5 mg + Ambroxol 30 mg/5ml of syrup	For productive cough	20-7-06
13.	Lamivudine 40 mg + Stavudine 10 mg dispersible tablet	For HIV infection	12-7-06
14.	Vitamin C 500 mcg + Zinc Citrate 2.2 mg + Selenium 60 mcg tablet	For Vitamin C deficiency	12-7-06
15.	Deferasirox dispersible tablet 125/250/500 mg	For chronic iron overload due to blood transfusion	10-7-06
16.	Zolpidem Tartrate E.R tablet (6.25 mg/12.5 mg)	For insomnia	10-7-06
17.	Solifenacin Succinate Tablet (5 mg/10 mg)	For overactive bladder with urge urinary incontinence urgency & urinary frequency	6-7-06
18.	Mebeverine HCl 135 mg + Isabgula husk 3.5 gm sachet	Irritable bowel syndrome	6-7-06
19.	Bimatoprost 300 mg + Timolol (as maleate) 5 mg/ml eye drops	For reduction of IOP	5-7-06
20.	Ceftriaxone (as sodium) 250 mg + Tazobactam 31.25 mg for injection (additional strength)	Antibiotic	5-7-06
21.	Bucizine HCl tablet (25 mg) & Syrup 6 mg/5 ml	As appetite stimulant	28-6-06
22.	Olmesartan 40 mg + HCTZ 25 mg tablet (additional strength)	Anti-hypertensive	28-6-06
23.	Levofloxacin 0.5% Ear drops	For otitis media	27-6-06
24.	Aspirin 150 mg + Clopidogrel (as bisulphate) 300 mg tablet (additional strength)	As loading dose for prevention of in-stent restenosis in PCI	22-6-06
25.	Methyl Prednisolone Aceponate Cream (0.1%)	For atopic dermatitis	15-6-06
26.	Ferrous ascorbate (equivalent to 50 mg Iron) + Folic acid 1.5 mg	For iron deficiency anaemia	8-6-06
27.	Olopatadine Ophthalmic solution (0.1%)	For allergic conjunctivitis	8-6-06

28.	Lopinavir 200 mg + Ritonavir 50 mg Tablet (additional strength)	Anti-HIV	8-6-06
29.	Amoxicillin 1000 mg + Clavulanate Potassium 62.5 mg E.R tablet	Antibiotic	8-6-06
30.	Lamotrigin 200 mg tablet (additional strength) dispersible tablet (5 mg/50 mg/100 mg/200 mg)	Anti-epileptic	8-6-06
31.	Icodextrin 7.5% peritoneal dialysis solution	For peritoneal dialysis	8-6-06
32.	Bemiparin Sodium Solution for injection (5000/7500/10,000 I.U)	For deep vein thrombosis	8-6-06
33.	Nadifloxacin (1%) + Miconazole Nitrate (2%) + Mometasone Furoate (0.1%) Cream	For dermatoses	6-6-06
34.	Amlodipine (as besylate) 5 mg + Metoprolol Succinate equivalent to Metoprolol Tartrate 50 mg	For hypertension	5-6-06
35.	Gatifloxacin (0.3%) + Prednisolone Acetate (1%) eye drops	For Ophthalmic use	2-6-06
36.	Cyclosporin Eye drops (0.1%) (additional strength)	For Ophthalmic use	2-6-06
37.	Perflutren liquid microsphere injectable suspension	For diagnostic use	31-5-06
38.	Zonisamide capsule 25/50 mg (additional strength)	Same as approved	25-5-06
39.	Ibandronic Acid Tablet 150 mg (additional strength)	Same as approved	25-5-06
40.	Levocetirizine 5 mg + Ambroxol Hydrochloride SR (75 mg) tablet	For production cough	24-5-06
41.	Nevibolol (as HCl) 5 mg + Amlodipine (as besylate) 5 mg/10 mg	For hypertension	24-5-06
42.	Itopride 150 mg capsule (S.R)	For GERD	22-5-06
43.	Ciclesonide rotacaps (200/400mcg)	For asthma	19-5-06
44.	Oxcarbazepine S.R 450 mg/900 mg (additional strength).	Anti-epileptic	19-5-06
45.	Pregabalin Capsule 25/50/100/200 mg (additional strength)	Same as approved.	19-5-06
46.	Olmesartan (as Medoxomil) 10 mg (additional strength)	Anti-hypertensive	18-5-06
47.	Midazolam (as maleate) 7.5 mg/15 mg tablet	For insomnia	10-5-06
48.	Formoterol Fumarate (6mcg) + Fluticasone Propionate (100/250/500mcg) dry powder inhaler	For asthma & COPD	10-5-06
49.	Nadifloxacin Gel 1%	Acne vulgaris	10-5-06
50.	Amlodipine (as besylate) 5 mg + HCTZ 12.5 mg Tablet	For hypertension	24-4-06
51.	Nicorandil E.R Tablet (10 mg/20 mg)	Angina Pectoris	24-4-06
52.	Atazanavir (100/150/200 mg)	Anti-HIV in adults.	24-4-06
53.	Oseltamivir formulation (additional indication)	For Prophylaxis of influenzae in adult and children > 14 years of age	24-4-06
54.	Pantoprazole (as Sodium) (E.C) 40 mg + Itopride (150 mg) S.R	For GERD	8-4-06
55.	D-trans Fentanyl Transdermal patches	For pain	5-4-06
56.	Resperidone Tablet & Syrup (additional Ind)	Acute mania & mixed episode in bipolar-I disorder.	4-4-06
57.	Doxofylline Syrup (20 mg/ml)	For bronchial asthma & COPD.	30-3-06
58.	Cholestyramine Powder for oral suspension (4gm/sachet)	For hypercholesterolaemia	30-3-06
59.	Haloperidol Tablet (0.5 mg) (additional Lower strength)	As approved earlier.	30-3-06
60.	Lactulose Enema (20%)	For constipation & hepatic encephalopathy	28-3-06
61.	Tobramycin Inhalation solution (300 mg/5ml)	For chronic pulmonary infection cystic fibrosis.	22-3-06

62.	Propionyl-L-Carnitine HCl Tablet (500 mg) & injection 300 mg/vial	Chronic congestive heart failure	22-3-06
63.	Eflornithine HCl Cream (139mg/gm)	For reduction of unwanted facial hair in women.	22-3-06
64.	Saquinavir (500 mg) tablet (additional strength)	Anti-AIDS	20-3-06
65.	Sodium Hyaluronate Cream 0.2%	For leg ulcer, diabetic ulcer etc.	16-3-06
66.	Cefditoren (as pivoxil) 200 mg tablet	Antibiotic	3-3-06
67.	Fluorescein Sodium Solution for Injection (100 mg/ml)	Ophthalmological diagnostic agent	2-3-06
68.	Diclofenac Sodium (75/50 mg) as (E.C) + Misoprostol 200mcg.	For OA & RA	28-2-06
69.	Atomoxetine 60 mg capsule (Addl. Strength)	For ADHD	27-2-06
70.	Levetiracetam Oral Solution (100 mg/ml).	Anti-epileptic	24-2-06
71.	Tenofovir Disoproxil Fumarate (300 mg) + Emtricitabine (200 mg) tablet	For HIV-1 infection	23-2-06
72.	Acetofenac 200 mg (S.R) tablet	NSAID	22-2-06
73.	Desflurane liquid for inhalation (240 mg/bottle).	For induction & maintenance of anaesthesia.	22-2-06
74.	Voriconazole Powder for oral solution (40 mg/ml)	Anti-fungal	21-2-06
75.	Cefetamet Pivoxil HCl oral suspension 250 mg/ml	Antibiotic	16-2-06
76.	Testosterone Transdermal Spray (12.5 mg/spray) (additional Lower strength)	For replacement therapy in males with Testosterone deficiency.	15-2-06
77.	Zanamavir inhalation powder 5 mg/blister	For influenza	13-2-06
78.	Doxofylline Tablet (400 mg)	For bronchial asthma & COPD.	8-2-06
79.	Metoprolol Succinate equiv. to Metoprolol Tartrate 50 mg + Amlodipine (as besylate) 5 mg	For hypertension	7-2-06
80.	Ciclesonide Inhaler 80/160mcg per actuation	For persistent asthma	6-2-06
81.	Pegaptinib Sodium Injection (0.3mg).	For neovascular (wet) age related macular degeneration.	6-2-06
82.	Dexibuprofen Tablet (200 mg/300 mg/400 mg)	For OA, RA & ankylosing spondylitis	6-2-06
83.	Moxifloxacin Eye Ointment (5 mg/gm)	For ophthalmic use	6-2-06
84.	Erdosteine Powder for oral suspension 35 mg/ml	For chronic obstructive bronchitis	6-2-06
85.	Tamsulosin HCl (MR) 0.4mg + Dutasteride 0.5 mg tablet	For BPH	6-2-06
86.	Atenolol 50 mg + HCTZ 25 mg (additional strength)	For hypertension	3-2-06
87.	Alendronate Sodium (equiv. to Alendronic acid 70 mg) + Cholecalciferol 70mcg (equiv. to 2800 IU Vit.D) Tablet	For osteoporosis	01-2-06
88.	Combikit of Tamsulosin HCl 0.4mg M.R capsule (10 no.) & Dutasteride Soft Gelatin Capsule 0.5 mg (10 no.)	For BPH	19-1-06
89.	Nebivolol (as HCl) 5 mg + Valsartan 80 mg	For hypertension	17-1-06
90.	Cefprozil Powder for oral suspension (125 mg/5ml)	Antibiotic	6-1-06
91.	Erdosteine 150 mg + Guaiphenesin 50 mg + Terbutaline 1.25 mg per 5ml syrup	Mucolytic	8-8-06
92.	Rosiglitazone (as maleate) 2mg + Glibenclamide 5 mg + MetFormin 500 mg tablet	Anti Diabetic	8-8-06
93.	L - Lysine HCl Ointment (150 mg/gm)	For wounds of various etiology	8-8-06
94.	Levocetirizine 2 HCl 5 mg+ Ambroxol HCl SR 75 mg + Pseudoephedrine HCl 120 mg SR Capsules	For SAR, PAR & Chronic idiopathic urticatia	9-8-06
95.	Alprazolam SR 0.25 mg + Sertraline (As HCl) 25 mg/50 mg tablet	For Panic disorder with or without agoraphobia	9-8-06

96.	Dexibuprofen 200 mg/300 mg + Paracetamol 500 mg tablet	For RA, OA & ankylosing spondylitis	10-8-06
97.	ISMN SR 60 mg + Metoprolol Succinate ER 25/50 mg	For angina & Hypertension	10-8-06
98.	Aspirin 75 mg/150 mg + Glycine 37.5 mg/75 mg tablet	For prevention of acute coronary syndrome in patients with CAD prophylaxis against stroke	10-8-06
99.	Combipack of 21 tablet of Quinine sulphate 600 mg each & 8 capsule of Doxycycline (as HCl) 100 mg each	For P. Falciparum malaria	10-8-06
100.	Pravastatin 40 mg tablet (Additional strength)	As approved	10-8-06
101.	Olanzapine powder for oral suspension (10 mg/5ml)	For schizophrenia in adults	11-8-06
102.	Cefepem (as HCl) 0.5/1gm + Amikacin (as sulphate) 0.125/0.250gm Inj.	Antibiotic	11-8-06
103.	Lamivudine 20 mg + Nevirapine 35 mg + Stavudine 5 mg tablet	Anti HIV	11-8-06
104.	Nadifloxacin (10 mg/gm) + Mometasone Furoate (1mg/gm) cream	For mixed infection of skin	17-8-06
105.	Premetrex (Disodium) powder for solution for Inj. 500 mg/vial	Anti Cancer	21-8-06
106.	Gliclazide 40 mg/80 mg + MetFormin HCl 500 mg + Rosiglitazone 2mg tablet	Anti-diabetic	22-8-06
107.	Tiropamide HCl (100 mg) tablet	For abdominal spasmodic pain, colics of hepatobiliary track, abdominal colics	22-8-06
108.	Eperisone HCl (50 mg) tablet	For neck-shoulder arm syndrome scapula hum oral per arthritis and low back pain	23-8-06
109.	Caroverine cap. 20 mg & Inj. 40 mg/2ml	For abdominal pain & tinnitus in adult	23-8-06
110.	Paclitaxel nanoparticle Inj. (20 mg/ml)	For metastatic breast cancer	23-8-06
111.	Amoxycillin 250 mg + Dicloxacillin 250 mg cap.	Antibiotic	28-8-06
112.	Rifaximin 200 mg tab.	For infections diarrhoea in adults	28-8-06
113.	Tigecycline powder For Inj. 50 mg/vial	For skin & skin structure infection & intra abdominal infection	28-8-06
114.	Stavudine SR 100 mg tablet	Anti HIV	29-8-06
115.	Cefixime (50 mg/100 mg) + Clavulanic acid 31.125 mg/62.5 mg per ml dry syrup & tablet	Antibiotic	29-8-06
116.	Ciclesonide 80 mcg/160 mcg + Formoterol 4.5 mg inhaler	Anti asthmatic	29-8-06
117.	Ciclesonide 100 mcg/ 200 mcg/400 mcg + Formoterol Fumarate 6 mg rotacaps	Anti asthmatic	29-8-06
118.	Abacavir Sulphate syrup 20 mg/ml	For HIV Infection	29-8-06
119.	S(-) pantoprazole (as sodium) 20 mg (E.C.) + Domperidone SR 30 mg tablet	For GERD	30-8-06
120.	Cefadroxil 500 mg + Clavulanic acid 125 mg tablet	Antibiotic	30-8-06
121.	Cefadroxil 250 mg + Clavulanic acid 62.5 mg dispersible tablet	Antibiotic	30-8-06
122.	Cefadroxil 250 mg + Clavulanic acid 62.5 mg per 5ml syrup	Antibiotic	30-8-06
123.	Human Insulin (r-DNA) Powder inhaler	For Type-I & Type-2 Diabetes	30-8-06
124.	Fulvestrant Inj. 250 mg/5ml pre-filled syringe	Anti Cancer	30-8-06
125.	S(-) Pantoprazole (as Sodium) Inj. 20 mg/vial	For peptic ulcer, GERD & Zollinger Ellison Syndrome	30-8-06
126.	Dasatinib tablet 20 mg/50 mg/70 mg tablet	For chronic Hepatitis B infection	30-8-06
127.	Telbivudine 600 mg tablet	For chronic Hepatitis B infection	30-8-06
128.	Aprepitant cap (80 mg/125 mg)	For chemotherapy induced nausea & vomiting	30-8-06

129.	Telmisartan 40 mg + Amlodipine (as Besylate) 5 mg tablet	For essential hypertension	30-8-06
130.	Gemifloxacin (as mesylate) 320 mg tablet	Antibiotic	30-8-06
131.	Ceftazidime 500 mg/1000 mg + Tazobactam (as sodium) 62.5 mg/125 mg per vial for injection	Antibiotic	30-8-06
132.	Cefepime (As HCl) 500 mg/1000 mg + Tazobactam (as Sodium) 62.5 mg/125 mg	Antibiotic	30-8-06
133.	Paromomycin Inj. 375 mg/ml	For visceral leishmaniasis (Kalaazar)	30-8-06
134.	Cefixime 100 mg + Cloxacillin (as Sodium) 500 mg + Lactobacillus (45 million spore) tab.	Antibiotic	31-8-06
135.	Alprazolam Dispersible Tab. 0.125 mg/0.25 mg/0.50 mg	For anxiety	20-9-06
136.	Epinastine HCl (0.05%) Ophthalmic solution	For allergic conjunctivitis	22-9-06
137.	Levofloxacin tablet (250 mg/500 mg) & Infusion 5 mg/ml (For additional indication)	For prostatitis	26-9-06
138.	Feracrylum 1% mouth gargle 10 mg/ml	As haemostatic agent in dental surgery	28-9-06
139.	Aceclofenac Inj. (150 mg/ml)	For pain in post operative & post traumatic cases	28-9-06
140.	Combipack of one cap. of aprepitant .125 mg & two cap. of aprepitant 80 mg each (combipack)	As Approved	10-10-06
141.	Formoterol fumarate 6mcg + Fluticasone propionate 50 mcg/125 mcg/250mcg MDI	For Asthma & COPD	14-10-06
142.	Amlodipine 25 mg + Metoprolol 25 mg (additional lower strength)		01-11-06
143.	Estrogen vaginal tablet 25 mcg	For atrophic vaginitis	2-11-06
144.	Esomeprazole 40 mg (E.C.) + Itopride 150 mg SR Capsules	For GERD	13-11-06
145.	Cefixime 200 mg + Cloxacillin 500 mg (ER) + Lactobacillus 90 million Spore tab. (additional strength)	Antibiotic	14-11-06
146.	Cefixime dispersible tablet 400 mg (new dosage form)	Antibiotic	22-11-06
147.	Trandolapril 1mg/2mg/4mg/2mg + Verapamil (ER) 240 mg/240 mg/240 mg/180 mg	Anti hypertensive	23-11-06
148.	Ciclesonide 160mcg/320mcg cap. for inhalation	Anti asthmatic	28-11-06
149.	Rabeprazole 20 mg (EC) + Itopride SR 150 mg	For GERD	28-11-06
150.	Metoprolol succinate 25 mg/50 mg ER + HCTZ 12.5 mg	Anti hypertensive	30-11-06
151.	Atorvastatin 5 mg + Fenofibrate 160 mg (additional strength)	As approved	01-12-06
152.	Aceclofenac Inj. 50 mg/ml (additional strength)	As approved	01-12-06
153.	Amisulpride 400 mg tablet (additional strength)	As approved	01-12-06
154.	Misoprostol tablet 25 mcg/100 mcg/ 200 mcg (additional strength indication)	For cervical ripening, prevention of post partum haemorrhage & First trimester of abortion with mifepristone	8-12-06
155.	Atazanavir 150 mg + Ritonavir 50 mg capsules	Anti HIV	12-12-06
156.	Mebeverine HCl 135 mg + Chlordiazepoxide 5 mg tablet	For IBS	12-12-06
157.	Ampicillin 250 mg + Dicloxacillin 250 mg tablet	Antibiotic	13-12-06
158.	Etoricoxib 10 mg + Methyl Salicylate 100 mg + Mentol 50 mg + Linseed oil 30 mg per gm. of Gel	For acute Musculoskeletal pain	14-12-06
159.	Racecadotril dispersible tablet (10 mg/30 mg) (new dosage Form)	For diarrhoea	15-12-06
160.	Gabapentin ER 450/600/900 mg tablet	For neuropathic pain & partial seizures	15-12-06

161.	Aceclofenac dispersible tablet 100 mg (new dosage form)	as Approved	21-12-06
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List of Drugs approved during January to December 2007

Sl. No.	Drug Name	Indication	Date of Approval
1.	R-Ondansetron (As HCl Dihydrate) (1 mg/ml) injection	Chemotherapy induced nausea & vomiting	12-1-07
2.	Torsemide 10 mg + Amiloride 5mg tablets	Edema associated with congestive heart failure & hypertension	17-1-07
3.	Fexofenadine Suspension (30 mg/5 ml)	Seasonal allergic rhinitis & chronic idiopathic urticaria	19-1-07
4.	Sildenafil Citrate 20 mg Tablet	For pulmonary arterial hypertension	23-1-07
5.	Pioglitazone 15 mg/30 mg + MetFormin ER 1000 mg tablet (Additional Strength)	As approved	23-1-07
6.	Fluvastatin Tablet (As calcium) 10 mg/20 mg/40 mg (Additional Strength)	As approved	29-1-07
7.	Halobetazone Propionate Cream (0.05%)	Corticosteroid responsive dermatoses	2-2-07
8.	Eszopiclone tablet (1 mg/2 mg/ 3 mg)	For insomnia	7-2-07
9.	Diltiazem HCl 2% gel	For anal fissure	7-2-07
10.	Nalbuphine injection 10 mg/20 mg per ml	For moderate to severe pain	7-2-07
11.	Levonorgestrel 1.5 mg tablets	For emergency contraceptive	7-2-07
12.	Pantaprazole Sodium 20 mg/40 mg Tablet (with Sodium Bicarbonate As buffer)	For gastric ulcer, duodenal ulcer, Z. E Syndrome, GERD	7-2-07
13.	Levofloxacin (250 mg/500 mg) + Ambroxol SR 75 mg tablet	For lower respiratory tract infection in adult	8-2-07
14.	Testosterone Cypionate (100 mg/200 mg) + Cotton seed oil 736/566 mg per ml injection	For testosterone deficiency (i) Primary hypogonadism (ii) Hypogonadotropic hypogonadism	8-2-07
15.	Rosiglitazone 1 mg + Metformin HCl 500 mg tablet (Additional Strength)	As approved	8-2-07
16.	Loteprednol Etabonate 5 mg + Tobramycin 3 mg per ml ophthalmic solution	For steroid responsive inflammatory ocular condition	14-2-07
17.	Amlodipine (As Besylate) 5mg + Metoprolol (As Succinate) ER 25 mg (Additional Strength)	As approved	14-2-07
18.	Glibenclamide 5 mg + Metformin SR 850 mg tablet (Additional Strength)	As approved	15-2-07
19.	Aceclofenac injection (150 mg/3 ml)	For short term treatment of pain due to post operative and post traumatic cases	19-2-07
20.	Metoprolol (As Succinate) 50 mg/ 25 mg ER) + Amlodipine 5 mg/2.5 mg tablet (For Additional Indication)	Angina pectoris in adults	20-2-07
21.	Ramipril 10 mg + HCTZ 12.5 mg tablet (Additional Strength)	As approved	20-2-07
22.	Amlodipine (As Besylate) 5 mg/5 mg/10 mg + Valsartan 80 mg/160 mg/160 mg tablet	Essential hypertension	21-2-07
23.	Glatiramer Acetate injection (20 mg/ml)	Multiple sclerosis	21-2-07
24.	Baclofen ER (GRS) Capsule 45 mg/60 mg (Additional Strength)	As approved	22-2-07
25.	Amlodipine (As besylate) 5 mg/10 mg + Perindopril 4 mg tablet	For hypertension	23-2-07
26.	Olopatadine HCl Tablet 2.5 mg/5 mg	Allergic nasal inflammation hives, itching with skin diseases	26-2-07

27.	Metoprolol (As Succinate) ER 25 mg/50 mg + Ramipril 2.5 mg/5 mg	Essential hypertension	26-2-07
28.	Rabeprazole Sodium 20 mg/10 mg with Sodium Bicarbonate as buffer	For Duodenal ulcer, G.U, Z.E.S. & GERD	26-2-07
29.	Ciclesonide 160 mcg/320 mcg + Formoterol Fumarate (12 mcg) (Dry powder inhaler additional strength)	As approved	27-2-07
30.	Moxonidine tablet 0.2 mg/0.3 mg/0.4 mg	For hypertension	27-2-07
31.	Ceftriaxone (As Sodium) 125 mg/250 mg + Sulbactam (As sodium) 62.5 mg/125 mg for injection (Additional Strength)	As approved	1-3-07
32.	Quetiapine (As Fumarate) SR 400 mg tablet (Additional Strength)	As approved	5-3-07
33.	Cabergoline 1mg tablet (Additional Strength)	For Hyperprolactinemia	6-3-07
34.	Levofloxacin Oral Solution (each 240 ml bottle contains Levofloxacin 125 mg/5 ml)	Antibiotic (For adult use only)	7-3-07
35.	Clindamycin 1% + Isotretinoin 0.05% gel	For acne	8-3-07
36.	Estradiol topical emulsion 2.5 mg/gm	Vasomotor symptoms Associated with menopause	16-3-07
37.	Levosalmamol MDI (50 mcg/actuation) & Dry Powder inhaler (100 mcg/ capsule) (New Dosage Form)	As approved	16-3-07
38.	Polonosetron (As HCl) for Injection 0.25 mg/5 ml	Chemotherapy induced nausea & Vomiting	20-3-07
39.	Cifixime 200 mg + Erdosteine 300 mg Capsules	Acute Exacerbation of chronic bronchitis	21-3-07
40.	Aminophylline CR 225/350 mg	Asthma, COPD, Bronchitis	21-3-07
41.	Etoricoxib 10 mg + Methyl salicylate 20 mg per gm of cream	Acute Musculoskeletal pain	21-3-07
42.	Eberconazole cream (1%)	Dermatophyte infection of skin such As T-corporis, T-c, T-Pedis	22-3-07
43.	ISMN 60 mg Sr + Atenolol 50 mg/100 mg	For angina pectoris	23-3-07
44.	Levonorgestrel 0.03 mg tablet	For control of fertility	23-3-07
45.	Bortezomib 2 mg/vial (Additional pack size)	As approved	28-3-07
46.	Comb kit of two capsule of Azaravir 150 mg each + 1 tablet of Ritonavir 100 mg)	For HIV infection	2-4-07
47.	Mecobalamine 500 mcg + Alpha Lipoic acid 100 mg Soft Gelatin capsule	For diabetic neuropathy	2-4-07
48.	Propofol 10 mg + Lignocaine 1 mg per ml injection	For induction of anesthesia	4-4-07
49.	Ezetimibe 10 mg + Fenofibrate 160 mg tablet	For combined hyperlipidemia	4-4-07
50.	Methylprednisolone Acetate topical solution 0.1%	Atopic dermatitis (eczema) inflammatory and allergic skin reaction	4-4-07
51.	Citicoline (750 mg) tablet (Additional Strength), syrup 500 mg/5 ml (new dosage form) (not for children)	As approved	10-4-07
52.	Ertapenem for injection (1 gm/vial)	Antibiotic	10-4-07
53.	Letrozole 2.5 mg tablet (for additional indication)	For induction of ovulation in anovulatory infertility (additional indication)	10-4-07
54.	Quetiapine SR Tablets 50mg (Additional Strength)	As approved	10-4-07
55.	Metoprolol (As Succinate) 25 mg + Amlodipine (As Besylate) 5 mg (Additional Strength)	As approved	10-4-07
56.	Sunitinib Maleate Capsules 12.5 mg/25 mg/50 mg	For G.I. Stromal tumor, advanced renal cell carcinoma	10-4-07
57.	Comb pack of 1 bottle of Ciprofloxacin Injection (200 mg/ 100 ml) & 1 bottle of Ornidazole injection 500 mg/100 ml)	Antibiotic	20-4-07

58.	Aprepitant 40 mg capsules (Additional Strength)	Prevention of post-operative nausea & vomiting (additional indication)	24-4-07
59.	Olopatadime Ophthalmic solution (0.2%) (Additional Strength)	As approved	24-4-07
60.	Combi pack of 1 tablet of Residronate sodium (35 mg) + 6 tablet of Calcium carbonate equivalent to 500 mg calcium each	For osteoporosis in postmenopausal women	1-5-07
61.	Levocetirizem 2 HCl Dispersible tablet (2.5 mg)	For allergic rhinitis & chronic urticaria	8-5-07
62.	Amlodipine (As Besylate) 10 mg + Perindopril 8 mg tablets (Additional Strength)	As approved	7-5-07
63.	Etodolac ER tablets 400 mg/500 mg	For osteoarthritis & rheumatoid arthritis	9-5-07
64.	Levosulpiride tablet (25 mg)	For G.I. problem like functional dyspepsia, nausea, vomiting and diabetic gastroparesis	10-5-07
65.	Rimonabant tablet 20 mg	For Obese Patients BMI \geq 30 kg/m ² or overweight patients BMI \geq 27 kg/m ² with Associated risk factors such As type-I diabetes or dyslipidemia	11-5-07
66.	Lactitol monohydrate Syrup 66.67/100 ml	For constipation	14-5-07
67.	S(-) Metoprolol (As Succinate) 25 mg + S(-) Amlodipine (As Besylate 2.5/5 mg	For essential hypertension	16-5-07
68.	Amlexanox Oral Paste (5%)	For aphthous ulcers in people with normal immune system	16-5-07
69.	Lenalidomide capsule (5mg/10mg/15mg/25mg)	For transfusion dependent anemia due to myelodysplastic syndrome associated with deletion 5q cytogenetic abnormality	16-5-07
70.	Cefotaxim (As Sodium) 0.5 mg/1 gm + Sulbactam (As Sodium) 250 mg/500 mg injection (for Additional Indication)	For surgical prophylaxis (additional indication)	18-5-07
71.	Lornoxicam tablet 4 mg/8 mg	For Osteoarthritis rheumatoid arthritis	21-5-07
72.	Atenolol 25 mg/50 mg + Indapamide SR 1.5 mg	For essential hypertension	21-5-07
73.	Livettiracetam concentration for infusion 100 mg/ml (new dosage form)	As adjunctive therapy in partial onset seizures in adults with epilepsy when oral administration is temporarily not feasible	21-5-07
74.	Eplerstat tablet 50 mg	For abnormality of vibration sense and abnormal change in heart rate associated with diabetic peripheral neuropathy	25-5-07
75.	Citicoline tablet 200 mg (Additional Strength)	As approved	25-5-07
76.	Varenicline (As Tartrate) 0.5 mg/ 1 mg tablets	As an aid to smoking cessation treatment in adults	29-5-07
77.	Azithromycin eye drops 1%	Conjunctivitis	6-6-07
78.	Ciclesonide Nasal Spray 50 mcg/spray	For seasonal & perennial allergic rhinitis in adults, adolescents aged \geq 12 years	8-6-07
79.	Ceftazidime 500 mg/1000 mg + Sulbactam (As Sodium) 250 mg/500 mg for injection	Antibiotic	8-6-07
80.	Isotretinoin 0.05% + Erythromycin 2% gel	For acne	8-6-07
81.	Aliskiren Tablet 150 mg/300 mg	For hypertension	8-6-07
82.	Glimepiride 1 mg/2 mg + Metformin SR 1000 mg tablet (Additional Strength)	As approved	8-6-07
83.	Cefditorene pivoxil dispersible tablet (30 mg/50 mg) (New Dosage form for children)	As approved	8-6-07
84.	Dexrabeprazole Sodium Enteric Coated tablet 5mg/10mg	For Duodenal ulcer, Gastric ulcer & GERD	13-6-07
85.	Renolazine Extend Release tablet (500 mg)	For Chronic Angina	14-6-07

86.	Phenytoin Sodium ER capsules (300 mg) (New dosage form)	For control of generalized tonic-clonic and treatment & prevention of seizures occurring during or following neurosurgery	14-6-07
87.	Alfuzocin HCl ER (10 mg) + Dutasteride 0.5 mg tablet	For BPH in men with enlarged prostate	14-6-07
88.	Cefepime injection 500 mg/1 gm/2 gm (For additional indication)	For bacterial meningitis in children	14-6-07
89.	Tranexamic acid mouthwash (50 mg/ml)	For prevention of oral hemorrhage in anticoagulant treated patients undergoing oral surgery	15-6-07
90.	Deflazacort oral suspension (6 mg/5 ml) (new Dosage Form)	As approved	15-6-07
91.	Tolterodine tartrate ER 4 mg + Tamsulocin HCl ER 0.4 mg tablet	For BPH with overactive bladder	15-6-07
92.	Omeprazole 20 mg/40 mg + Sodium Bicarbonate 1100 mg capsules	For duodenal ulcer, gastric ulcer & GERD	15-6-07
93.	Dexrabeprazole Sodium E. coated tablet 5mg/10mg	For duodenal ulcer, gastric ulcer and GERD	13-6-07
94.	Cefepime Injection (New indication)	For bacterial meningitis in children	14-6-07
95.	Phenytoin Sodium E.R. (300mg)	For control of generalised tonic-clonic (grand-mal) and prevention and treatment of seizures occurring during or following neurosurgery	14-6-07
96.	Tranexamic acid Mouth Wash (50mg/ml)	For prevention of oral hemorrhage in anticoagulant treated patients undergoing oral surgery	15-6-07
97.	Deflazacort Oral Suspension (6mg/5ml) (New dosage form)	For asthma, rheumatoid arthritis when glucocorticosteroid therapy is warranted	15-6-07
98.	Tolterodine Tartrate 4mg (ER) + Tamsulosin HCl 0.4mg Capsule	For BPH with overaction bladder in Adults only	15-6-07
99.	Omeprazole (E.coated) 40mg + Sodium Bicarbonate 1100mg capsule	For gastric ulcer, duodenal ulcer and GERD	18-6-07
100.	Mebeverine HCl prolonged release capsule (200mg)	For irritable bowel syndrome	19-6-07
101.	Azithromycin 500mg + Ambroxol S.R (75mg) Tablet	For RTI caused by susceptible organisms in adults	5-7-07
102.	Pholcodiene Syrup (4mg/5ml)	For symptomatic relief of dry ticklish and unproductive coughs in children above 1 years	6-7-07
103.	Exenatide Injection pre-filled pen (250mcg/ml)	For adjunctive therapy to improve glycemic control in patients with Type-II diabetes mellitus, who have not achieved adequate glycemic control with Metformin, a sulfonyl urea or a combination of metformin and sulfonylurea	6-7-07
104.	Moxifloxacin HCl (0.5%) + Ketorolac Tromethamine 0.5% Ophthalmic Solution	For reduction of post-operative inflammatory conditions of the eyes	11-7-07
105.	Levofloxacin (15mg) + Prednisolone Acetate 10mg per ml eye drops	For post-operative steroid responsive inflammatory ocular conditions when ocular bacterial infections or a risk of bacterial infection exists	11-7-07
106.	Loteprednol Etabonate (0.5%) + Levofloxacin (1.5%) Eye drops	For post-operative steroid responsive inflammatory ocular conditions when ocular bacterial infections or a risk of bacterial infection exists	12-7-07
107.	Clotrimazole (10mg) + Methyl-prednisolone aceponate 1mg/gm of cream	For fungal infection of skin associated with inflammation	12-7-07

108.	Capecitabin Tablet (150mg/ 500mg) (for additional indication)	(i) First line treatment of advanced gastric cancer in combination with platinum based regimen. (ii) Treatment of patients with locally advanced or metastatic breast cancer in combination with docetaxel following failure of cytotoxic chemotherapy	16-7-07
109.	Rifabutin Capsule (150mg)	For treatment of pulmonary T.B. only in patients co-infected with HIV. (It should never be used as a substitute to Rifampicin in T.B. patients without HIV co-infection)	16-7-07
110.	Lapatinib (as Ditosylate) (250mg) Tablet	In combination with capecitabine it is indicated in patients with advanced or metastatic breast cancer whose tumour overexpress HER2 and who have received prior therapy including trastuzumab	24-7-07
111.	Levocetirizine Di-HCl mouth dissolving tablets (5mg) (new dosage form)	For the treatment of allergic rhinitis and chronic urticaria	25-7-07
112.	Idaravone Injection (1.5mg/ml)	For improvement of neurologic symptoms, disorders of activities of daily living and functional disorder associated with acute ischemic stroke	26-7-07
113.	Diclofenac Sodium (75mg/ml) Injection (Additional Strength)	For management of painful conditions in post-operative cases, rheumatoid arthritis and osteoarthritis	30-7-07
114.	Cefpodoxime (as Proxetil) (100mg/200mg) + Clavulanic acid (62.5/125mg) tablet	For LRTI, URTI and UTI	30-7-07
115.	Atorvastatin (40mg) + Ezetimibe (10mg) Tablet (Additional Strength)	As approved	30-7-07
116.	Cefepime (250mg) + Tazobactam (31.25mg) Injection (Additional Strength)	As approved	30-7-07
117.	VSL #3 (Probiotic Blend) sachet	For rotavirus diarrhoea in children	31-7-07
118.	Sorafenib (as Tosylate) (200mg) Tablet	For advanced renal cell carcinoma	31-7-07
119.	Methylcobalamin (500mcg) + Alpha Lipoic Acid (100mg) + Pyridoxine (3mg) + Folic acid (1.5mg) Soft Gelatin Capsule	For diabetic neuropathy	31-7-07
120.	Halobetasol Propionate (0.5mg) + Salicylic Acid 30mg per gm of ointment	For plaque psoriasis	1-8-07
121.	Combipack of 12 tablet of Artesunate (50mg) each + 3 tablet of each containing Sulfadoxine (500mg) + Pyrimethamine (25mg) Tablet. (Additional Strength)	As Approved	1-8-07
122.	Omeprazole (20mg/40mg)+Sod. Bicarbonate-600mg+ Mg.Hydroxide-700mg chewtab	For duodenal, gastric ulcer, GERD, and erosive esophagitis	1-8-2007
123.	Deferasirox dispersible tablet (400mg) (Additional Strength)	As approved	17-8-07
124.	Tegafur (100mg) + Uracil (224mg) capsule	For first line treatment of metastatic colorectal cancer in combination with Calcium folinate	22-8-07
125.	Bortezomib Injection (Additional Indication)	For the treatment of patients with mantle cell lymphoma who have received at least one prior therapy	5-9-07
126.	Amlodipine (5mg) + Nebivolol (5mg) tablet (Additional Strength)	As approved	6-9-07
127.	Ceftazidime (2gm) + Sulbactam (1gm) Injection (Additional Strength for Additional Indication)	For serious abdominal infection.	6-9-07

128.	Polyethylin Glycol 400 (0.4%) + Propylene Glycol (0.3%)	For temporary relief of dryness, irritation burning, stinging, grittiness or foreign body sensation caused due to environmental factors	18-9-07
129.	Resperidone E.R. (long-acting) injection (12.5mg/vial) (Additional Strength)	As approved	25-9-07
130.	Levocetirizine Di-HCl syrup (2.5mg/5ml) (For use in children 2 years and above)	As approved	26-9-07
131.	R-Sibutramine Capsule (2.5mg/5mg)	As an adjunctive therapy for the management of obesity including weight loss and maintenance of weight loss in patients whose BMI is 30Kg/m ² or higher	26-9-07
132.	Cefuroxime Axetil (250mg) + Clavulanic Acid (125mg) Tablet	For adult patients with infection caused susceptible micro-organisms including S.aureus viz UTI, upper and lower RTI and gonococcal urethritis	27-9-07
133.	Sulphur Hexafluoride Powder and solvent for dispersion for injection (45mcg/ml)	For diagnostic use in echocardiography doppler of macrovasculature and doppler of microvasculature	28-9-07
134.	Ondansetron orally disintegrating tablet (4mg/8mg) (Additional dosage form)	For chemotherapy induced nausea and vomiting	28-9-07
135.	Cefuroxime Axetil (250mg) + Clavulanic acid (125mg) tablet	For UTI, URTI and LRTI and gonococcal urethritis	5-10-07
136.	Cefuroxime-125/250/500mg + Clav. Acid-31.25/62.5/125mg	For adult patients with infection caused by susceptible microbes, including S.aureus, (e.g-UTI, Upper & lower RTI & gonococcal urethritis)	10/05/07
137.	Amiodarone Injection (Additional Indication)	For cardiopulmonary resuscitation in the event of cardiac arrest related to ventricular fibrillation resistant to external electric shock	5-10-07
138.	Risedronate Sodium tablet (35mg) (Additional Indication)	For osteoporosis in men at high risk of fracture	8-10-07
139.	Sucralfate (70mg) + Metronidazole (10mg) + Povidone Iodine (50mg) per gram of ointment	For infected wounds and ulcers	9-10-07
140.	Levetiracetam Tablet (Additional Indication)	(i) As monotherapy in partial onset seizures with or without secondary generalisation in patients with 16 years of age with newly diagnosed epilepsy. (ii) As adjunctive therapy in myoclonic seizures in adults and adolescents from 12 years of age with Juvenile myoclonic epilepsy. In primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy	9-10-07
141.	Combipack of two tablet of chloroquine phosphate (250mg) each + 14 tablet of Proguanil HCl (100mg) each	For drug resistant malaria	10-10-07
142.	Paclitaxel (protein bound particle) for injectable suspension (paclitaxel (100mg) + Albumin Human 900mg per 20ml	For breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy	11-10-07
143.	Olmesartan Medoxomil (20mg) + Amlodipine Besylate (5mg) Tablet	For mild to moderate hypertension	15-10-07
144.	Atorvastatin Calcium (10mg) + Ramipril (2.5mg/5mg) tablet	For treatment of patients with both hypertension and hypercholesterolemia	15-10-07
145.	Omeprazole (20mg) + Sodium bicarbonate (1100mg) tablet (Additional Strength)	As approved	15-10-07
146.	Moxifloxacin HCl (5mg) + Prednisolone Acetate (10mg) per ml (eye drops)	For inflammation after ocular surgery and where a risk of bacterial ocular infection exists	16-10-07

147.	Methylcobalamine (500mcg) + Alpha Lipoic acid (100mg) + Pyridoxine HCl (1.5mg) + Thiamine (2mg) + Calcium Picolinate (200mg) tablet	For diabetic neuropathy	16-10-07
148.	Satranidazole (300mg) + Ofloxacin (200mg) Tablet	For diarrhoea of mixed infection in adults	18-10-07
149.	Methylcobalamin 500mcg+beta carotene-10.33mg+alpha lipoic acid 100mg+B6 1.5mg+B1 2mg & Cr.polynicotinate	For adult patients with diabetic neuropathy	18-10-07
150.	Calcium Pidolate equivalent to Calcium 500mg + Vit-D3 250 IU	For osteoporosis and calcium deficiency state	23-10-07
151.	Etizolam Tablet (0.5mg/1mg)	For anxiety disorder associated with depression	29-10-07
152.	Oxaprozine Tablet (600mg)	For relief of signs and symptoms of osteoarthritis, rheumatoid arthritis	30-10-07
153.	Prulifloxacin (600mg) Tablet	For acute uncomplicated lower urinary tract infection (simple cystitis), complicated lower UTI, acute exacerbation of chronic bronchitis	30-10-07
154.	Cilostazole E.R. Tablet (100mg/200mg)	For management intermittent claudication	30-10-07
155.	Atorvastatin Calcium (10mg) + Fenofibrate (145mg) (Additional Strength)	As Approved	30-10-07
156.	Sitagliptin Tablet (25mg/50mg/100mg)	As adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes	30-10-07
157.	Miglitol (50mg) + Metformin HCl SR (500mg) tablet	For adult with Type-II diabetes mellitus where simple drug therapy, diet and exercise do not result in adequate glycemic control	31-10-07
158.	Mupirocin (2%) + Methylprednisolone Aceponate (0.1%) Cream	For atopic dermatitis	31-10-07
159.	Methyl cobalamine 500mcg+Folic acid1.5mg+B5-5mg,+Zn.sulphate 25mg+Cr.Polynicotinate 200mcg+Selenium-65mcg+Inositol-1.5mg + Alpha lipoic acid -100mg capsule	For vitamins and mineral deficiency states	31-10-07
160.	Methylcobalamine 500mcg+Folic acid1.5mg+ Alpha lipoic acid -300mg +Benfetiamin-50mg capsule	For diabetic neuropathy	13-11-07
161.	Methyl prednisolone aceponate-1mg + Salicylic acid-50mg ointment	For treatment of psoriasis	19-11-07
162.	Propanol 50gm+Povidone iodine-1gm in 100ml solution	For surgical & hygienic hand disinfection	19-11-07
163.	Propanol-18 gm+Ethenol(100%)-45gm in 100ml solution	-do-	19-11-07
164.	Voglibose dispersible tab.0.2mg/0.3mg	As Approved	20-11-07
165.			
166.	Ceftriaxone-2gm+ Tazobactam 250mg for injection	As Approved	21-11-07
167.	Methylprednisolone aceponate-1mg + Mupirocin-20mg cream	For the treatment of atopic dermatitis	21-11-07
168.	Citicholine (As Sod.)-200mg/500mg/750mg granules per sachet	As Approved	26-11-07
169.	Butarphenol tartrate 10mg/ml nasal spray	For management of pain in patients using opioid analgesics	26-11-07
170.	Deferasirox 100mg dispersible tablet (Additional Strength)	As Approved	28-11-07
171.	Methyl cobalamine 500mcg+Folic acid1.5mg+B6-3mg+Zn.sulphate 61.8mg+Ca.Pantothenate 10mg+ Niacinamide-50mg +Chromium-50mcg capsule	For vitamins and mineral deficiency patients	29-11-07

172.	Methylcobalamine 500mcg+Folic acid 1.5mg+ Alpha lipoic acid-100mg+B6-3mg+Thiamine 10mg capsule	For diabetic neuropathy	29-11-07
173.	Doxophylline-400mg+Salbutamol (as sulphate)-2mg/4mg tablets	For treatment of Bronchial asthma in adults	29-11-07
174.	Gatifloxacin (As Sequihydrate)-3mg + Flurbiprofen sod.-0.3mg/ml eye drops	For reduction of post-operative inflammatory conditions of eye, when bacterial infection exists	29-11-07
175.	Sertanidazole-300mg+ Ofloxacin-200mg tablet	For treatment of diarrhoea of mixed infection in adults patients	29-11-07
176.	Zoledronic acid 5mg/100ml solution for infusion (Additional Indication)	Post-menopausal osteoporosis	6-12-07
177.	Olmesartan medoximil-20mg + Ramipril-5mg tablet	For treatment of essential hypertension	6-12-07
178.	Levosulpiride Tablet (50mg/100mg) (Additional Strength for Additional Indication)	For depression and schizophrenia in adults	6-12-07
179.	Combipack of 12 Artesunate -50mg tablets & 6 Mefloquin-250mg tablets	For drug resistant P.falciparum malaria infection	6-12-07
180.	Pregabalin-75mg/150mg +Methylcobalamine 500mcg cap	For the treatment of adult patients with peripheral neuropathy	10-12-07
181.	Doxycycline-100mg +L.bacillus spores-5 billion	For adult patients prone to intra-adominal bacterial infection & Antibiotic associated diarrhoea	11-12-07
182.	Cefprozil 250mg/500mg+Clav. Acid-62.5mg /125mg tab	For the treatment of adult patients with upper & lower RTI, Skin & Skin structure infection	11-12-07
183.	Dextrometharpahan HBr-10mg+Chlorphenaramine maleate-2mg /5ml syrup	For the temporary relief of cough due to throat irritation, sneezing & running nose	11-12-07
184.	Lomoxicam 8mg /2ml inj	For short-term treatment of mild to moderate pain, when oral administration is inappropriate(i.e. after dental surgery)	11-12-07
185.	Apomorphine HCl-2mg/3mg Sublingual tablet	For erectile dysfunction in adult men	11-12-07
186.	Escitlopram (as Oxalate)10mg + Clonazepam-0.5mg tablet (Additional Strength)	For comobid depression and anxiety disorder	12-12-07
187.	Doxophylline injection-10mg/ml	For bronchial asthma & COPD in adult patients, when oral therapy is inappropriate	31-12-07

List of Drugs approved during January to December 2008

Sl. No.	Drug Name	Indication	Date of Approval
1.	Me-salicylate 30% +Menthol 10% + Camphor 4% Cream	For temporary relief from pain, swelling & inflammation due to musculoskeletal disorder	29-11-2007
2.	Voglibose 0.2mg/0.3mg tablet (Mouth dissolving)	For improvement of parantial hyperphemia in diabetes mellitus only. When diet and/or exercise or oral, hypoglycaemic drug or insulin preparation in addition to diet and or exercise do not result in adequate glycemic control	28-12-2007
3.	Hydroxychloroquine 400mg tablets (Additional Strength)	Same as Approved	31-1-2008
4.	ISMN 30 mg SR+Metoprolol Succinate equivalent to Metoprolol Tartrate 25mg/ 50mg tablets (Additional Strength)	Same as Approved	2-1-2008
5.	Halobetasol 0.05%+Clotrimazole 1.0% cream	For the treatment of steroid responsive fungal infections including eczema and psoriasis	4-1-2008

6.	Citicholine Syrup 750mg/5ml	For the treatment of disturbance of consciousness resulting from head injuries, brain operation and acute stage of cerebral infraction in adults only	4-1-2008
7.	Levodopa 200mg + Carbidopa 50mg C.R. tablet	For Parkinson's Disease	8-1-2008
8.	Nanocrystalline Silver Gel 0.002%	For the treatment of burns of wound infections	4-1-2008
9.	Cinitapride (as Hydrogen tartrate) 1mg tablet	For the treatment of gastroesophageal reflux disease and functional inconveniences of the gastrointestinal motility	4-1-2008
10.	Tenofovir disoproxil fumarate 300mg + Lamivudine 300mg tablet	For the treatment of adult patients with HIV infection	7-1-2008
11.	Cefixime 200mg/100mg+Lactic acid bacillus 2.5 billion spores tablet & dispersible tablet	For the treatment of Urinary tract infections, respiratory tract infections, biliary tract infections in adult patients prone to antibiotic associated diarrhoea	7-1-2008
12.	D-Trans Fentanyl Metrix system (12mcg/hr) (Additional Strength)	Same as Approved	7-1-2008
13.	Ceftazidime 500mg+Tobramycin 60mg per vial (Injection)	For the treatment of lower respiratory tract infection caused by pseudomonas aeruginosa	8-1-2008
14.	Atazanavir 300mg capsules (Additional Strength)	Same as approved	8-1-2008
15.	Ertapenem for injection 1gm/vial (Additional Indication)	For the prophylaxis of surgical site infections following elective colorectal surgery	15-1-2008
16.	Vildagliptin Tablets 50mg/100mg	As an adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes mellitus	18-1-2008
17.	Atorvastatin 10mg+Aspirin 75/150mg Capsules	For the treatment of dyslipidemia associated with atherosclerotic arterial disease with risk of myocardial infarction, stroke or peripheral vascular disease	18-1-2008
18.	Sumatriptan (as Succinate) 50mg+ Naproxen Sodium 550 mg tablets	For the treatment of acute migraine	22-1-2008
19.	Sodium Valproate 666mg + Valproic acid 290 mg equivalent as Sodium valproate 1000 mg C.R. tablet (Additional Strength)	Same as Approved	24-1-2008
20.	Cefepime (as Hydrochloride) 2000/1000/500mg + Sulbactam (as Sodium) 1000/500/250 mg per vial of injection	For serious CRTI, uncomplicated and complicated UTI, Uncomplicated skin & skin structure, infection acute exacerbation of chronic bronchitis & intra-abdominal infection	24-1-2008
21.	Paclitaxel Nanoparticle Solution for injection 20mg/ml (Additional Indication)	Ovarian cancer, non-small cell lung cancer and AIDS related Kaposi Sarcoma	22-1-2008
22.	Sorafenib tablets 200mg (Additional Indication)	For Hepatocellular Carcinoma	22-1-2008
23.	Zanamvir inhalation powder 5mg/blister (Additional Indication)	For prophylaxes and treatment of both influenza A&B in adults and children (greater than or equal to 5 years)	22-1-2008
24.	Mycophenolate Mofetil Capsule 250mg, 500mg & Oral suspension 200mg/ml (Additional Indication)	For the prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplantation	23-1-2008
25.	Combikit 4 tablets of Alendronate sodium trihydrate equivalent to Alendronic acid 70mg each + 24 tablets of Calcium carbonate 1250mg (equivalent to 500 mg Calcium) + Cholecalciferol-250IU	For the treatment of osteoporosis in post-menopausal women	23-1-2008
26.	Acetofenac injection 150mg/ml	For short term treatment of pain due to post operative and post traumatic cases	23-1-2008
27.	Atorvastatin 10mg + Fenofibrate 80mg tablet (Additional Indication)	For the treatment of uncomplicated and complicated UTI, uncomplicated skin and skin structure infections, and complicated intra-abdominal infections	25-1-2008

28.	Sodium Valproate 499.5mg+ Valproic acid 217.5mg equivalent as Sodium Valproate-750mg CR tablet (Additional Strength)	Same as Approved	24-1-2008
29.	Diclofenac 50mg+ Serratiopeptidase 10mg enteric coated tablet	For the treatment of acute pain in adults	24-1-2008
30.	Gabapentin 100mg+Methylcobalamin 500mcg tablets (Additional Strength)	Same as Approved	24-1-2008
31.	Cefpirome (as Sulphate) 500/1000mg/2000mg + Sulbactam (as Sodium) 250mg/500mg/1000mg powder for injection	For the treatment of infection caused by sensitive organisms viz. lower RTI, complicated UTI, Septicaemia, bacteremia	24-1-2008
32.	Metformin HCl ER 500 mg + Fenofibrate 80mg/160mg tablet	For the treatment of Type-II diabetes associated with mixed dyslipidemia	25-1-2008
33.	Salicylic acid 10mg/20mg (Foaming facewash solution)	For the treatment of acne vulgaris	28-1-2008
34.	Ozagrel HCl tablets 100 mg/200mg	For the treatment of bronchial asthma	28-1-2008
35.	Rivastigmine transdermal patch (each patch of 5m ² , 10m ² , 15m ² and 20m ² contain Rivastigmine base 9/18/27/36 mg respectively)	For the treatment of patient with mild to moderately severe dementia of the Alzheimer type and dementia associated with Parkinsons disease	28-1-2008
36.	Daptomycin powder for concentrate solution for infusion (350mg/500mg per vial)	For the treatment of complicated skin and skin structure infections and for staphylococcus aureus blood-stream infections (bacteremia)	28-1-2008
37.	Dextromethorphan Orodispersible strip 5.5 mg/11mg	For the relief of persistent dry irritating cough in adult patients only	28-1-2008
38.	Diclofenac sodium 50mg + Dicyclomine HCl 20 mg per ml of injection	For the treatment of acute colicky pain in adults	28-1-2008
39.	Travoprost 40mcg+ Timolol (as Maleate) 5 mg per ml of eye drops	For decrease of intraocular pressure in patients with open angle glaucoma or ocular hypertension, who are insufficiently responsive to topical beta blockers or prostaglandin analogues	28-1-2008
40.	Amoxicillin 250mg/125mg + Cloxacillin 250mg/125mg + Lactic Acid Bacillus 1.7 Billion spores	For RTI, SRS of tissue infection, bones & joint infection, ENT infection in adults prone to antibiotic associated diarrhoea	30-1-2008
41.	Amoxicillin 250mg + Lacto-Bacillus 1.7 billion Spores	For RTI, SRS of tissue infection, bones & joint infection, ENT infection in adults prone to antibiotic associated diarrhoea	31-1-2008
42.	Amoxycillin 250mg + Cloxacillin 250mg+Lactobacillus 2 billion spores capsules	For the treatment of lower RTI, skin & soft tissue bone & joint infections, ENT infections in adult patients prone to antibiotic associated diarrhoea	30-1-2008
43.	Tiotropium (as Tiotropium Bromide Monohydrate) 18mcg + Formoterol Fumarate Dihydro 12mcg + Ciclesomide 400mcg per capsules	As 3rd line treatment of severe cases of COPD when monotherapy and second line therapy with two drugs do not respond adequately	31-1-2008
44.	Metoprolol Succinate Equivalent to Metoprolol Tartrate [ER 25/50mg] + Atorvastatin (As Calcium) 10 mg tablets	For the treatment of patient with both essential hypertension and hypercholesterolemia	28-1-2008
45.	Levocetirizine Di HCl Dispersibel tablet 5mg/10mg (New Dosage form)	For allergic rhinitis & chronic urticaria	28-1-2008
46.	Oseltamivir 30mg & 45 mg Capsules (Additional Strength)	Same as Approved	28-1-2008
47.	Fondaparinux Sodium injection (Additional Indication)	Treatment of acute coronary syndrome (ACS) with and without ST-segment elevation	28-1-2008
48.	Camostat Mesylate tablets 100mg	For remission of acute symptoms of chronic pancreatitis and post-operative reflux esophagitis	29-1-2008
49.	Hyaluronic Acid Slat 25mg + Cross-Linked Hyaluronic acid 25mg per ml in prefilled syringe	For intradermal implantation and facial soft tissue augmentation	30-1-2008

50.	Ursodeoxycholic acid tablets 600 mg	For the treatment of patients with chronic cholestatic liver disease	30-1-2008
51.	Dalteparin Sodium Injection (Additional Indication)	For the extended treatment of symptomatic venous thromboembolism (VTE) proximal deep thrombosis (DVT) and/or pulmonary embolism (PE), to reduce the recurrence of VTE in patients with cancer	30-1-2008
52.	Beclomethasone Dipropionate 0.25mg +Econazole 10mg+ Neomycin 5mg per gm of Cream	For the topical treatment of bacterial and fungal infections	30-1-2008
53.	Exenatide injection (Each 2ml vial contains-Exenatide 5mcg/10mcg per 0.2ml) Additional Strength)	For adjunctive therapy to improve glycemic control in patients with type-II diabetes mellitus, who have not achieved adequate glycemic control with metformin, a silyfonylurea or a combination of metformin and a silyfonylureas	30-1-2008
54.	Diclofenac Sodium 50mg+Pacacetamol 500mg tablets	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis	30-1-2008
55.	Gabapentin SR 600 mg tablets	As adjunctive therapy in the treatment of partial seizures of epilepsy	30-1-2008
56.	Memantine 5mg/10mg+Donepezil 5 mg Tablets	For moderate to severe Alzheimer's disease	31-1-2008
57.	Doxifluridine Capsules 100mg/200mg	For carcinoma of the stomach, colon, rectum, breast, uterine, cervix and bladder	31-1-2008
58.	Haemodialysis Powder/Liquid Form containing citrate	For use for patients being treated by hemodialysis	31-1-2008
59.	Carmustine (Polifeprosan 20 with carmustine Implant (Wafer)	1. In newly diagnosed high-grade malignant glioma patients as an adjunct to surgery and radiation. 2. In recurrent glioblastoma multiforme patients as an adjunct to surgery	31-1-2008
60.	Cimetropium Bromide tablet 50mg	For the treatment of irritable bowel syndrome	31-1-2008
61.	Cyclobenzaprine HCl Tablets 5mg/10mg	As adjunct to rest and physical therapy for relief of muscle spasm associated with acute painful musculoskeletal conditions	31-1-2008
62.	Sertaconazole Nitrate Cream 2%	For the topical treatment of the superficial mycosis like dermatophytosis	31-1-2008
63.	Cefpodoxime 50mg+Clavulanic acid 31.25mg dispersible tablet & dry syrup (Additional Strength)	Same as Approved	31-1-2008
64.	Darifenacin (as Hydrobromide) 7.5 mg/15mg ER tablets	For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency	31-1-2008
65.	Amoxycillin 125mg/250mg/500mg + Lactobacillus 1.66 billion Spores (Capsules)	For the treatment of respiratory tract infection, skin and soft tissue infections & antibiotics associated diarrhoea in adult patients	31-1-2008
66.	Halobetasol 0.5mg+Miconazole 20mg per gram cream	For steroid responsive dermatoses associated with superficial fungal infection of skin	31-1-2008
67.	Montelukast 10mg+Levocetirizine 5mg film coated tablets	For the treatment of allergic rhinitis in adults only	31-1-2008
68.	Hydroquinone 2% + Tretinoin 0.025% (w/w) Momentasone 0.10% Gel	For short term intermittent treatment of moderate to severe melasma of the face in the presence of measures for sun avoidance including use of sun screen	31-1-2008
69.	Phenylephrine 5mg+ Chlorpheniramine maleate 0.5mg + Paracetamol 125 mg + Sodium citrate 60mg+Menthol 1mg (per 5ml) Syrup	For the treatment of common cold and cough associated with fever	31-1-2008

70.	Diclofenac Sodium 100mg (SR Pellets) + Rabepazole Sodium 20mg (E.C Pellets) Capsules	For treatment of painful inflammatory conditions associated with gastroduodenal ulcers	31-1-2008
71.	Ciclesonide 16mcg+320mcg/Formoterol 12mcg+Tiotropium 18mcg Dry powder inhaler	As third line treatment of severe cases of COPD, when monotherapy and second line therapy with two drugs do not respond adequately	31-1-2008
72.	VSL# (Combination of Lactic acid bacteria (VSL#3)	For the treatment of irritable bowel syndrome	31-1-2008
73.	Clostimethate Sodium of 1,00,000 IU Injection	For the treatment of serious infection caused Gram-Ve bacteria including LRTI, UTI, where commonly used anti-bacterial agent may be infective because of bacterial resistance	31-1-2008
74.	Ramipril 5mg+HCTZ 12.5mg tablets (Additional Strength)	Same as Approved	20-2-2008
75.	Metronidazole CR tablet 600mg	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis	21-2-2008
76.	Quetiapine fumarate SR tablets	For the additional indication “acute manic episode associated with bipolar disorder	21-2-2008
77.	Atorvastatin Calcium 80mg tablets (Additional Strength)	Additional strength (it should not be used routinely because of increased risk of adverse events. It should be reserved for patients who are considered to be at higher risk after careful risk assessment	25-2-2008
78.	Euphorbia Prostrata Dry Extract (Ethanol 80% (v/v) (35-70): 100 mg tablet	For the treatment of haemorrhoid	29-2-2008
79.	Amtolmetin Guacil tablets 600mg	For the treatment of osteoarthritis & rheumatoid arthritis	7-3-2008
80.	Brimonidine Tartrate Ophthalmic solution 0.1% (with Purite as preservation 0.0005%) (Additional Strength)	For lowering of IOP in patients with open angle glaucoma ocular hypertension	7-3-2008
81.	Methoxsalen USP-20mg Tablet	1. For repigmentation of idiopathic vitiligo along with phototherapy. 2. For symptomatic control of severe, recalcitrant, disabling psoriasis in conjunction with phototherapy	7-3-2008
82.	Cefditoren pivoxil 400mg tablets (Additional Strength)	Same as Approved	11-3-2008
83.	Doxofylline ER tablets 400mg/800mg (Additional Strength)	For the treatment of bronchial asthma & COPD in adults	12-3-2008
84.	Betamethasone 0.05% + Miconazole 2% Cream	For the treatment of steroid responsive dermatoses associated with superficial fungal infections of the skin	12-3-2008
85.	Premetrxed disodium injection 100mg/vial (Additional Strength)	Same as Approved	12-3-2008
86.	Omeprazole 20mg/40mg+Sodium bicarbonate 1680mg per sachet powder for oral suspension	For gastric ulcer, duodenal ulcer and GERD	12-3-2008
87.	ISMN 30mg SR+Atenolol 50mg tablets (Additional Strength)	Same as Approved	19-3-2008
88.	Temozolamide capsules 140mg/180mg (Additional Strength)	Same as Approved	31-3-2008
89.	Amisulpiride 300mg tablets (Additional Strength)	Same as Approved	20-3-2008
90.	Nifedipine SR Tablets 10mg/20mg	For the treatment of essential hypertension	24-3-2008
91.	Ambroxol HCl 15mg+Guiphenesin 50mg+Terbutalin sulphate 1.25mg+Menthol 2.5mg per 5ml of syrup	For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis	26-3-2008
92.	Ambroxol HCl 30mg + Guaiphenesin 100mg+Terbutaline sulphate 2.5mg per 10ml syrup	For the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis	26-3-2008
93.	Boswellia Serrata 0.05gm/gm of cream	For the treatment of mild to moderate psoriasis	28-3-2008
94.	Etoricoxib injection 90mg/ml	For short term use in acute painful condition in adults only	28-3-2008

95.	Drospirenone 3mg+Ethinyl estradiol 0.02mg tablets (Additional Strength)	Oral contraceptive in women	28-3-2008
96.	Nimesulide 100mg ER + Levocetirizine HCl 5mg Tablets	For symptomatic treatment of acute rhinosinusitis	28-3-2008
97.	Dexketoprofen (as Trometamol) tablets 12.5mg/25 mg	For the treatment of mild to moderate pain, such as dental pain, dysmenorrhoea & musculoskeletal pain	28-3-2008
98.	Nepafenac Ophthalmic suspension (1mg/ml)	For the treatment of pain and inflammation associated with cataract surgery	31-3-2008
99.	Hylan GF 20 Injection (Synvisc) (Additional Indication)	For pain management in patients suffering with osteoarthritis of the knee, hip, shoulder and ankle	31-3-2008
100.	Docetaxel injection conc.	For additional indication "advanced gastric adenocarcinoma, locally advanced squamous cell carcinoma of head & neck, Hormone refractory metastatic prostate cancer, locally advanced or metastatic breast cancer	31-3-2008
101.	Methylcobalamin 1000 mcg + Pyridoxine HCl IP 100mg+Nicotinamide IP 100mg+D-Panthenol IP 50mg per 2 ml of injection	For peripheral neuropathy	31-3-2008
102.	Lamivudine 20mg + Stavudine 5mg dispersible tablets (Additional Strength)	Same as Approved	1-4-2008
103.	Nicardipine HCl Injection 2.5mg/ml	For short-term treatment of hypertension when oral therapy is not feasible or not desirable	7-4-2008
104.	Diclofenac Potassium 50mg+ Serratiopeptidase (as enteric coated pellets) 15 mg capsules (Additional Strength)	For the treatment of acute pain in adults	8-4-2008
105.	Diacerin 50mg+Aceclofenac 100mg tablets	For the treatment of adult patients with osteoarthritis of knee and or hip joints	11-4-2008
106.	Rabepazole Sodium Enteric coated pellets 15.4% w/w (20mg/129.83mg)	Same as Approved	16-4-2008
107.	Live freeze-dried Lactic acid bacteria and Bifidobacteria capsules	For the treatment of irritable bowel syndrome	10-4-2008
108.	Miltefosin Capsule 10mg/50mg (Additional Indication)	Treatment of cutaneous leishmaniasis	16-4-2008
109.	Silver Wound Dressing	As an antimicrobial barrier for management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic)	16-4-2008
110.	Diacerin 50mg+Glucosamine sulphate 500mg tablets	For the treatment of adult patients with osteoarthritis of knee and hip joints	21-4-2008
111.	Clostridium Botulinum type-A toxin haemagglutinin complex (Additional Indication)	For focal spasticity, including the treatment of arm symptoms associated with focal spasticity in conjunction with physiotherapy	22-4-2008
112.	Fluconazole Dispersible tablets 50mg	For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy	22-4-2008
113.	Lenalidomide Capsule 5mg/10mg/15mg/25 mg (Additional Indication)	In combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy	22-4-2008
114.	Sitagliptin (As Phosphate) 50mg+ Metformin HCl 500mg/1000mg film coated tablets	As an adjunct to diet & exercise to improve glycemic control in patients with type-two diabetes mellitus	28-4-2008
115.	Lansoprazole for injection 30mg/vial	For short term treatment of erosive esophagitis when patients are unable to take the oral formulation	28-4-2008

116.	Naproxen Suspension 125mg/5ml	For the treatment of RA in children 5 years of age and above	28-4-2008
117.	Sevelamer Carbonate 400mg/800mg tablets & sachet 400mg/800 mg	For control of serum phosphorus in patients with chronic kidney disease on dialysis	28-4-2008
118.	Rabeprazole Sodium (With Sodium bicarbonate as buffer) 10mg/20mg tablets	For the treatment of gastric ulcer, duodenal ulcer, Zollinger Ellison Syndrome and GERD	28-4-2008
119.	Pantoprazole Sodium (With Sodium bicarbonate as buffer) 20mg/40mg tablets	For the treatment of gastric ulcer, duodenal ulcer, Zollinger Ellison Syndrome and GERD	28-4-2008
120.	Cefdinir 250mg dispersible tablets and oral suspension 250mg/5ml	For the treatment of community acquired pneumonia, acute exacerbation of chronic bronchitis, uncomplicated skin and skin structure infection, Pharyngitis/tonsillitis	29-4-2008
121.	Pregabalin capsules (Additional Indication)	Management of fibromyalgia syndrome	29-4-2008
122.	Pregabalin 75mg/150mg + Methylcobalamin 750mcg capsules (Additional Strength)	Same as Approved	8-5-2008
123.	Aliskiren 150/150/300/300mg+HCTZ 12.5/25/12.5/25mg tablets	For the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on monotherapy	8-5-2008
124.	Desmopressin lyophilisate Oral tablets 60mcg/120mcg/240mcg per tablets	For diabetes insipidus and nocturnal enuresis	8-5-2008
125.	Losartan Potassium 25mcg + Amlodipine (as Besylate) 5mg tablets (Additional Strength)	Same as Approved	14-5-2008
126.	Lecithin Liquid (each 5 ml contains Lecithin 500mg equivalent to essential Phospholipids 250mg)	For alcoholic liver disease, drug induced hepatitis	14-5-2008
127.	Halobetasol 0.05% + Salicylic acid 6% Ointment (Additional Strength)	For the treatment of plaque psoriasis	14-5-2008
128.	Benzoyl Peroxide Medicated Solution (each textured pad contains 4.5%/6.5%/8.5% of solution)	For the topical treatment of acne vulgaris	14-5-2008
129.	Deflazocort 24mg tablets (Additional Strength)	Same as Approved	14-5-2008
130.	Sodium Chondroitin sulphate 40mg + Sodium Hyaluronate 30mg per ml Intraocular Injection (Additional Strength)	For use as a surgical aid in anterior segments procedure including cataract extraction & intra-ocular lens implantation	14-5-2008
131.	Esomeprazole (with Sodium bicarbonate as buffer) 20mg/40mg tablets	For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome	14-5-2008
132.	Telmisartan 40mg + Atorvastatin (as Calcium) 10 mg Tablets	For coexisting essential hypertension & hyperlipidemia	22-5-2008
133.	Milnacipran HCl 25mg/50mg equivalent to Milnacipran free base 21.77 or 43.55 mg tablet	For the treatment of adult patients with major depressive disorder	22-5-2008
134.	Metolazone 2.5mg + Losartan Potassium 25mg/50mg tablets	For hypertension in patients whose blood pressure is not adequately controlled in monotherapy	28-5-2008
135.	Metolazone 2.5mg + Ramipril 2.5mg/5mg	For essential hypertension in adult patients whose blood pressure is not adequately controlled on monotherapy	28-5-2008
136.	Doxercalciferol 0.5mcg/2.5mcg Soft Gelatin capsules	For the treatment of secondary hyperthyroidism in patients with chronic kidney disease on dialysis	29-5-2008
137.	Acebrophylline Capsules 100mg	For the treatment of adult patients with chronic obstructive pulmonary disease and bronchial asthma	29-5-2008
138.	Sofalcone Capsule (100mg/50mg)	For the treatment of gastric ulcer and management of gastric mucosal lesions (erosion, haemorrhage, redness or edema) associated with acute gastritis or acute exacerbation of chronic gastritis	2-6-2008

139.	S(+) Etodolac ER tablets 200mg/300mg	For the relief of pain and inflammation in patients with rheumatoid arthritis and osteoarthritis	2-6-2008
140.	Diclofenac Sodium 50mg+Codeine Phosphate 50mg tablets	For the treatment of adult patients with signs & symptoms of acute painful conditions	2-6-2008
141.	Sodium Hyaluronate injectable gel (each 0.6 ml 1 ml pre-filled syringe contains Sodium Hyaluronate 20mg/ml, 22.5mg/ml)	For intradermal implantation and facial soft tissue augmentation	3-6-2008
142.	Amphotericin B Lipid suspension injection (25 mg/vial) with lipid suspension	For invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin B therapy	3-6-2008
143.	Dexrabeprazole 10mg (EC) + Domperidone 30mg SR Capsules	For the treatment of Gastroesophageal Reflux Disease (GERD) in patients not responding to dexrabeprazole alone	09-6-2008
144.	Thiocolchicoside 4mg/8mg + Ketoprofen 50mg/100mg tablets	For acute low back pain & other musculoskeletal painful and inflammatory condition in adults	11-6-2008
145.	Cefotaxime sodium + Sulbactam sodium for injection (Additional Indication)	For the treatment of lower respiratory tract infection in children	24-6-2008
146.	Artemether 40mg/80mg+ Lumefantrine 240mg/480mg tablets (Additional Strength)	Same as Approved	24-6-2008
147.	Ivabradine (HCl) 5mg/7.5mg Tablets	For the treatment of chronic stable angina pectoris in patients with normal sinus rhythm who have a contraindication or intolerance for Beta-blockers	3-7-2008
148.	Amino Acid, Glucose Parenteral Solution (Solution for intravenous infusion)	Indicated to meet daily requirement of nitrogen (amino acids), energy (glucose) for patients needing parenteral Nutrition	8-7-2008
149.	Temoporfin 1mg/ml Injection (Additional Strength)	Same as Approved	8-7-2008
150.	Pazufloxacin Mesylate i.v. infusion 300mg/100ml & 500mg/100ml	For the treatment of RTI, UTI and abdominal infections in adults	9-7-2008
151.	Metoprolol ER + Amlodipine tablets (Additional Indication)	For coronary artery disease/ischaemic heart disease	16-7-2008
152.	Fenofibr Disoproxil fumarate 300mg + Lamivudine 300mg + Efavirenz 600mg tablets		18-7-2008
153.	Vildagliptin 50mg/50mg/50mg + Metformin HCl +850 mg + 1000mg tablets	For the treatment of type-II diabetes mellitus when single drug therapy along with diet, exercise do not result in adequate glycemic control	21-7-2008
154.	Testosterone Undecanoate 250mg/ml Injection	For Testosterone replacement therapy of male hypogonadism when testosterone deficiency has been confirmed by clinical feature or biochemical tests	22-7-2008
155.	Abatacept powder for injection 250mg/vial	For adult patients with severe active rheumatoid arthritis who had an inadequate response to one more DMARDs such as methotrexate or TNF antagonists	22-7-2008
156.	Actarit 100mg Tablets	For the treatment of rheumatoid arthritis patients	22-7-2008
157.	Tenofovir Fumarate 300mg+Lamivudine 300mg+Efavirenz 600mg Tablets	For the treatment of HIV infection in adults	23-7-2008
158.	Bacillus Clausii Spores (2 Billion) Capsules (Additional dosage form)	Same as Approved	23-7-2008
159.	Gatifloxacin 0.3% + Ketorolac Tromethamine 0.4% Eye Drop	For reduction of post operative inflammatory condition of eyes	24-7-2008
160.	Ketorolac Tromethamine 4mg+Gatifloxacin 3mg Eye Drops	For the reduction of post-operative inflammatory conditions of the eye	24-7-2008

161.	Cefadroxyl (as Monohydrate) 125 mg + Clavulanic acid (as Potassium) 31.25 per 5ml Syrup (Additional Strength)	Same as Approved	25-7-2008
162.	Doxercalciferol (0.5/ 2.5mcg) Soft Gelatin Capsule (Additional Indication)	For the treatment of secondary hyperparathyroidism in patients with Stage 3 or Stage 4 chronic kidney disease	5-8-2008
163.	Artemether + Lumefantrine Dispersible tablet (40/80mg + 240/480mg) (Additional Strength)	Same as approved	5-8-2008
164.	Ceftazidime + Tobramycin injection (1 gm + 120mg) (Additional Strength)	Same as approved	5-8-2008
165.	Olopatadine Nasal Spray (0.6%)	For the relief of the symptoms of seasonal allergic rhinitis in patients 12 years of age and older	5-8-2008
166.	Loxoprofen Sodium tablet (60mg)	For the symptomatic treatment of pain and inflammation condition in patients with osteoarthritis	14-8-2008
167.	Dexibuprofen Suspension 50mg/ 5ml	For the treatment of mild to moderate pain, reduction of fever	14-8-2008
168.	Bromfenac Sodium Eye Drop (0.09%)	For the treatment of post-operative inflammation & reduction of post-operative ocular pain in patients who have undergone cataract extraction	14-8-2008
169.	Ceftriaxone + Sulbactam injection (Additional Indication)	For the treatment of acute bacterial otitis media, skin & soft structure infections, UTI, uncomplicated gonorrhoea, pelvic inflammatory disease, bacterial septicemia, bone and joint infections, intra abdominal infections, meningitis, surgical prophylaxis	18-8-2008
170.	Citicoline Chewable tablet (500mg)	For the treatment of disturbance of consciousness as resulting from head injuries, brain operation and acute stage of cerebral infraction in adult only	18-8-2008
171.	Ambroxol + Loratadine + Guaifenesin Syrup (30mg + 5mg + 50mg per 5ml)	For the treatment of productive cough	18-8-2008
172.	Ferrous Ascorbate + Folic Acid + Zinc FC Tablets (100mg + 1.5 mg + 22.5 mg)	For the treatment of iron deficiency anaemia	18-8-2008
173.	Cyclobenzaprine 7.5mg tablets (Additional Strength)	Same as approved	18-8-2008
174.	S-Metoprolol Succinate Oral Solution (Each ml contains: S-Metoprolol Succinate 9.5mg equal to S-Metoprolol Tartrate 10mg)	For the treatment of haemo-dynamically stable patients with definite or suspected acute Myocardial Infarction to reduce cardio-vascular mortality.	19-8-2008
175.	Doxorubicin HCl Pegylated Liposomal Injection (20/50MG) (Additional Indication)	In combination with Bortezomab for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant	23-8-2008
176.	Povidone Iodine sachet (Containing Effervescent Granules). Each 2gm sachet contains: 175mg (Available Iodine 17.5mg)	As mouthwash for oral hygiene in various oropharyngeal conditions, surgery, dental infections, and halitosis	25-8-2008
177.	Sodium Chondroitin Sulphate + Sodium Hyaluronate injection (40mg + not more than 17mg per ml)	Same as approved	25-8-2008
178.	Metolazone + Spironolactone FC Tablets (2.5/5mg + 50mg)	For the treatment of oedema associated with congestive heart failure, cirrhosis and nephritic syndrome	25-8-2008
179.	Tretinoin Microsphere Gel (0.1% w/v)	For topical treatment of acne vulgaris	26-8-2008
180.	Misoprostol 50mcg tablet (Additional Strength)	Same as approved	26-8-2008
181.	Ferrous Ascorbate + Folic Acid suspension (Equiv. to elemental iron 30mg + 550mcg per 5ml) (New dosage form)	Same as approved	27-8-2008

182.	Guaiphenesin ER Tablet (600mg)	For the treatment of productive cough accompanied by phlegm	28-8-2008
183.	Clopidogrel 300mg Tablet (Additional Strength)	As approved	2-9-2008
184.	Capecitabine 150/500mg Tablets (Additional Indication)	For the treatment of patients with metastatic colorectal cancer	2-9-2008
185.	Lopinavir + Ritonavir (100 + 25mg) Tablets (Additional Strength)	For the treatment of patients with HIV infection	8-9-2008
186.	Ixabepilone lyophilized powder inj. 15mg/45mg per vial	In combination with Capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an Anthracycline and a Taxane, or whose cancer is Taxane resistant and for whom further Anthracycline therapy is contra-indicated	13-9-2008
187.	Halometasone (as monohydrate) 0.05% Cream	For the relief of inflammatory and pruritic manifestation of non-infected corticosteroid responsive dermatoses like eczema	13-9-2008
188.	Calcium and Magnesium 24% (Veterinary) injectable solution.	For the treatment of milk fever, hypocalcaemia tetanics and disorders of calcium metabolism in dairy cattle.	13-9-2008
189.	Telmisartan + Ramipril (40mg + 2.5mg) Tablets (Additional Strength)	For the treatment of essential hypertension	15-9-2008
190.	Drotaverine + Aceclofenac (80mg + 100mg) Tablets	For the treatment of adult patients with muscular pain associated with spasm	15-9-2008
191.	Losartan + Chlorthalidone (25/25/50/50mg + 6.25/12.5/6.25/12.5mg) Tablets	For the treatment of mild to moderate hypertension in adult patients whose blood pressure is not adequately controlled by monotherapy	15-9-2008
192.	Olmesartan + Ramipril (5mg + 40mg) tablets (Additional Strength)	For the treatment of essential hypertension	15-9-2008
193.	Fluconazole + Zinc Pyrethron (Each 30/60ml bottle contains: 2% + 1%) Lotion	For the treatment of seborrhoeic dermatitis	15-9-2008
194.	Citicoline CR Tab 1000mg	For the treatment of patients with serious cerebral injuries of vascular traumatic nature with or without loss of consciousness & for treatment of degenerative damages & chronic cerebral vascular injuries in senile dementia.	16-9-2008
195.	Montelukast Suspension 5mg/5ml	For the treatment of Prophylaxis & chronic treatment of Asthma in pediatrics patients 12 months of age & older For relieving symptoms of seasonal allergic rhinitis in pediatric patients 2 years of age & older & perennial allergic rhinitis in pediatric patients 6 months of age & older	16-9-2008
196.	Etoricoxib roll on Topical Solution 1% v/v	For the treatment of pain, swelling & inflammatory conditions due to arthritis	16-9-2008
197.	Risedronate Sodium 150mg Tablet (Additional Strength)	As already approved	16-9-2008
198.	Levosulpiride Inj. 25mg/ml, 2ml	For the treatment of depression and schizophrenia in adults when oral therapy is not possible	26-9-2008
199.	Paliperidone ER Tablet 3mg/6mg/9mg	For the acute and maintenance treatment of schizophrenia	26-9-2008
200.	Ceftiofur Crystalline free acid Suspension equi to Ceftiofur ---- 200 mg(veterinary)	For treatment of bovine respiratory disease (BRD, Shipping fever, pneumonia) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in beef, non-lactating dairy, and lactating dairy cattle	26-9-2008

201.	Ceftiofur HCl Suspension (As HCl salt)---- 500mg (veterinary)	For treatment of sub-clinical mastitis in dairy cattle at the time of dry off associated with <i>Staphylococcus aureus</i> , <i>Streptococcus dysgalactiae</i> , and <i>Streptococcus uberis</i>	26-9-2008
202.	Ceftiofur HCl Suspension (as HCl salt) --- 125mg (veterinary)	For treatment of clinical mastitis in lactating dairy cattle associated with coagulase- negative staphylococci, <i>Streptococcus dysgalactiae</i> , and <i>Escherichia coli</i>	26-9-2008
203.	Nitrofurantoin SR Tab. 100mg	For the treatment of acute uncomplicated urinary tract infections (acute cystitis) caused by susceptible strains of <i>Escherichia coli</i> or <i>Staphylococcus saprophyticus</i>	26-9-2008
204.	Tolperisone HCl Tablet 50/100/ 150 mg	For the relief of painful muscle spasms of the skeletal musculature	26-9-2008
205.	Etoricoxib + PCM (60mg + 500mg) Tablets	For the short term use in acute painful and inflammatory condition	30-9-2008
206.	Citicoline Oral Drops	For the treatment of disturbance of consciousness resulting from head injuries, brain operation & acute stage of cerebral infraction in adult	30-9-2008
207.	Paracetamol + Meloxicam + Benzyl Alcohol + Lignocaine (5mg/ml + 150mg/ml + 1% + 1%) Injection	Indicated for the treatment of mastitis, metritis, pneumonia, pleuritis, fever and relieving of acute pain in musculoskeletal disorders in animals	30-9-2008
208.	Calcium (as Calcium Citrate Malate) + Colecalciferol (as Colecalciferol Concentrate) + Folic Acid (250mg + 100IU + 50mcg) Tablets	For the treatment of calcium and Vitamin D deficiency states (pregnancy, lactation, growing children)	30-9-2008
209.	Artemether + Lumefantrine (80mg + 480mg/5ml) Dry syrup	For the treatment of chloroquine resistant/multidrug resitant on complicated malaria	30-9-2008
210.	Cabergoline 1mg Tablets (Additional indication)	For the treatment of hyperprolactinemia and inhibition of lactation	1-10-2008
211.	Pemetrexed disodium 500 mg/100 mg powder for sol. (Additional Indication)	In combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology	8-10-2008
212.	Tylvalosin tartrate oral soluble granules sachet 62.5% w/w (Veterinary)	For the prevention and treatment of mycoplasma induced chronic respiratory disease in broilers and breeders, the prevention and treatment of diseases due to <i>Clostridium perfringens</i> (necrotic enteritis, wet litter, cholangiohepatitis), the prevention and treatment of <i>Ornithobacterium rhinotracheale</i> (ORT)	8-10-2008
213.	Bortezomib inj.3.5mg/vial (Additional Indication)	Treatment of patients with multiple myeloma	9-10-2008
214.	Sertaconazole Nitrate Vaginal Tab.500mg	For the treatment of vulvo-vaginal candidiasis in women	9-10-2008
215.	Fosfomycin Tromethamine sachet 3 gms	For the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of <i>E.Coli</i> and <i>Enterococcus faecalis</i>	9-10-2008
216.	Ixabepilone lyophilized powder (Additional Indication)	As monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to cytotoxic chemotherapy. Previous therapy should have included as anthracycline, a taxane, and capecitabine	9-10-2008
217.	Eprosartan Mesylate 400 mg/600 mg Tablets	For the treatment of essential hypertension	11-10-2008
218.	Tretinoine Gel as Micro Sphere 0.04% 0.1%	For topical treatment of Acne vulgaris	14-10-2008
219.	Hydroxychloroquine Sulphate (Additional Indication)	For the treatment of systemic lupus erythematosu	17-10-2008

220.	Budesonide + Formoterol (80/160 mcg + 4.5mcg) Inhalational Powder (Additional Indication)	Indicated in the regular treatment of patients with moderate to severe COPD with frequent symptoms and a history of exacerbations	17-10-2008
221.	Azithromycin + Dexamethasone (10mg + 1mg) Eye Drops	For post-operative steroid responsive inflammatory ocular condition when bacterial ocular infections or a risk of bacterial ocular infections exists.	21-10-2008
222.	Diclofenac + Thiocolchicoside (50mg (EC) + 8mg) Capsules	For the treatment of acute inflammation conditions associated with spasm in adults only	21-10-2008
223.	Adapalene 0.1% + Benzoyl Peroxide 2.5% gel	For the treatment of acne vulgaris	24-10-2008
224.	Aceclofenac Roll - On 1%	For the treatment of acute musculoskeletal pain in patients	24-10-2008
225.	Citicoline Troches 200/500mg	For the treatment of patients with serious cerebral injuries of vascular traumatic nature with or without loss of consciousness and for treatment of degenerative damages and chronic cerebral vascular injuries in senile dementia	31-10-2008
226.	Amisulpride S.R. Bilayered tablet 200/400mg	For acute and chronic schizophrenic disorders, in which positive symptoms and or negative symptoms are prominent, including patients characterised by predominant negative symptoms	3-11-2008
227.	Calcitriol + Calcium + Zinc (0.25mcg + 200mg + 7.5mg) Capsules	For the treatment of hypocalcaemia and/or osteoporosis	4-11-2008
228.	Atazanavir + Ritonavir (300mg + 100mg) FC Tablets	For the treatment of patients with HIV infection	4-11-2008
229.	Timolol Maleate SR Eye Drops 5.0 mg/ml	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open angle glaucoma	8-11-2008
230.	Rosuvastatin Calcium tablets 5/10/ 20/40 mg (Additional Indication)	(1) As an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. (2) As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels	8-11-2008
231.	Paclitaxel inj. 30/100/300mg vial (Additional Indication)	For the treatment of advanced gastric carcinoma	8-11-2008
232.	Montelukast + Desloratidine (10mg + 5mg) FC Tablets	For the treatment of allergic rhinitis in adults only	10-11-2008
233.	Amlodipine + Metoprolol (2.5/5 mg + 25/50mg (ER)) Tablets	Additional Lower Strength	10-11-2008
234.	Losartan + HCTZ (100 mg + 25 mg) Tablets	Additional Strength	10-11-2008
235.	Phenylramidol HCl tablet 400mg	For the treatment of lumbago, integumental pain, musculoskeletal pain	14-11-2008
236.	Salicylic Acid + Coal Tar (3% + 1%) Solution	For scaling of seborrhea, seborrheic dermatitis, psoriasis of scalp	17-11-2008
237.	Salicylic Acid + Coal Tar + Precipitated Sulphur (3% + 1% + 3%) Ointment	For the treatment of psoriasis and fungal skin infection	17-11-2008
238.	Thiocolchicoside + Etoricoxib (4mg + 60 mg) FC Tablets	For the acute treatment of inflammatory musculoskeletal disorders associated with painful muscle spasm in adults	17-11-2008
239.	Tamsulosin + Tolterodine (0.4mg MR Pellets + 2mg/4mg ER Pellets) Capsules	Additional Lower Strength	17-11-2008
240.	Calcium Hypochlorite 4gm Sachet (Calcium Hypochlorite 0.542% Other Ingredients: 99.458%)	For purification of contaminated ground water sources	23-11-2008
241.	Sumatriptan + Naproxen (50mg + 275mg) Tablets	Additional Lower Strength	24-11-2008

242.	Amoxycillin + Clavulanic acid(1 gm + 62.5mg) FC Tablets	For the treatment and management of patients with community acquired pneumonia or acute bacterial sinusitis due to beta lactamase producing pathogens	25-11-2008
243.	Buprenorphine + Naloxone (2 mg/0.4mg + 0.5/0.1 mg) Tablets	Additional Lower Strength	2-12-2008
244.	Atorvastatin + Metformin(10mg + 500mg SR) Tablets	As adjunctive therapy to diet and exercise in patients with diabetic dyslipidemia	4-12-2008
245.	Pemetrexed disodium 500 mg/100 mg powder for solution (Additional Indication)	As monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology	4-12-2008
246.	Magnesium Valproate Tablet 200mg/400mg	For the treatment of generalized or partial seizures as monotherapy or adjunctive therapy. For the treatment of maniac episodes associated with bipolar disorders. For prophylaxis of migraine headache in adults	4-12-2008
247.	Ursodeoxycholic Acid 300/600 SR Tablets (Additional Strength)	For the dissolution of Radiolucent choledochal gall stone, chronic cholestatic liver disease in particular primary biliary cirrhosis, primary sclerosing cholangitis & cholestasis associated with cystic fibrosis	8-12-2008
248.	Rifampicin + INH + Piperine (200mg + 300mg + 10mg) Capsules	For the treatment of adult patients with pulmonary tuberculosis	11-12-2008
249.	Rifampicin +Piperine (200mg+ 10mg) Capsules	For the treatment of adult patients with pulmonary tuberculosis	11-12-2008
250.	Amphotericin B Lipid suspension 50mg/ vial (Additional Strength)	Additional Strength	12-12-2008
251.	Desmopressin Acetate tablet 0.1/0.2 mg	For the treatment of cranial diabetes insipidus, primary nocturnal enuresis in patients.	12-12-2008
252.	Mifepristone + Misoprostol (1 tab of mifepristone 200mg and 4 tab of misoprostol 200mcg) Combipack	For the medical termination of intrauterine pregnancy (MTP) of up to 63 days gestation based on the first day of the last menstrual period	16-12-2008
253.	Lamotrigine MR Tablets 50/100 mg	For the treatment of bipolar I disorder (Additional Indication)	17-12-2008
254.	Levosulpride Injection 25mg/2ml (Additional Strength)	For the treatment of different gastro-intestinal problems like functional dyspepsia, nausea, vomiting & diabetic gastroparesis. For the treatment of schizophrenia and depression in adults	17-12-2008
255.	Cyclobenzaprine HCl ER Capsule 15/30mg	As an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful, musculoskeletal conditions	17-12-2008
256.	Docetaxel injection concentrate 80mg/2ml, 20mg/0.5ml (Additional Indication)	In combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with locally advanced squamous cell carcinoma of the head and neck	17-12-2008
257.	Salicylic Acid + Cetyl Alcohol + Stearyl Alcohol (2% + 2.65% + 0.26%) Lotion	For the treatment of scaly dermatoses	18-12-2008
258.	Azathioprine 25mg Tablets	Additional Strength	19-12-2008
259.	Paracetamol solution for infusion 10mg/ml	For short term treatment of moderate pain, especially following surgery and for the short term treatment of fever, when administration by i.v route is clinically justified	23-12-2008
260.	Gemifloxacin + Ambroxol (320mg + 75mg SR) FC Tablets	Indicated for the treatment of lower respiratory tract infections in adult patients	24-12-2008

261.	Ceftazidime + Sulbactam (500/ 1000mg + 250/500mg) Injection	1. For LRTI infections, 2. For UTI - Complicated and uncomplicated, 3. For bacterial septicemia, 4. For bone and joint infections, 5. For gynaecologic infections including endometritis, pelvic cellulitis and other infections of female genital tract, 6. For CNS infections including meningitis	24-12-2008
262.	Paracetamol + Phenylephrine Hydrochloride (Each 6gm sachet contains: 500mg + 10mg)	For the treatment of fever associated with cold, nasal congestion in adults	24-12-2008
263.	Carboinoxamine Maleate + Ammonium Chloride + Sodium Citrate (Each 5 ml contains: 2 mg + 120 mg + 120 mg) syrup	For symptomatic treatment of cough	24-12-2008
264.	Diclofenac + Thiocolchicoside (50 mg + 4 mg) Capsules	Additional Lower Strength	24-12-2008

List of Drugs approved during January to December 2009

Sl. No.	Name of Drug	Indication	Date of Approval
1.	Zoledronic Acid Injection 5 mg/100 ml (Addl. Indication)	For the treatment of osteoporosis in post-menopausal women and in men who are at increased risk of fracture, including those with a recent low-trauma hip fracture	7-1-2009
2.	Misoprostol Tablet 600 mcg	Addl. Strength	9-1-2009
3.	Acebrophylline Syrup 10 mg/ml	For the treatment of adult patients with chronic obstructive pulmonary disease (COPD) and bronchial asthma	9-1-2009
4.	Selamectin Tropical solution (For verterinary use) 60 mg/120 mg per ml	(I) For the treatment and lasting prevention of flea infestations, treatment and control of flea allergy dermatitis, prevention of heartworm disease, treatment and prevention of ear mites in dogs and cats; (II) For the treatment and prevention of sarcoptic mange, roundworms and for control of tick infestations in dogs	9-1-2009
5.	Methylcobalamin 1500 mcg + Calcium 200 mg + Calcitriol 0.25 mcg + Folic Acid 1.5 mg + Pyridoxine 3 mg Capsules	For the treatment of vitamin deficiency states in adults	14-1-2009
6.	Metoprolol tartrate tablets 50 mg (Addl. Indication)	Adjunct to the treatment of Hyperthyroidism	14-1-2009
7.	Cinaclet (as HCl) Tablet 30/60/90 mg	For the treatment of secondary hyper parathyroidism in patients with chronic kidney diseases (CKD) on dialysis and for hypercalcemia in patients with parathyroid carcinoma	14-1-2009
8.	Mycophenolate mofetil Capsules 250 mg, Tablets 500 mg, Oral suspension 200 mg/ml (Addl. Indication)	For the prophylaxis of acute organ rejection in patients receiving allogeneic hepatic transplantation	23-1-2009
9.	Liquid Paraffin 1.25 ml + Milk of Magnesia 3.75 ml + Sodium Picosulphate 3.33 mg per 5 ml	For symptomatic treatment of constipation in adults	29-1-2009
10.	Ranolazine 1000 mg ER Tablets (Additional Strength)	Same as approved	31-1-2009
11.	Hyaluronic acid (cross linked) Pre-filled syringe 18 mg/0.6 ml and 24 mg/0.8 ml	For intradermal implantation and facial soft tissue augmentation	31-1-2009
12.	Caspofungin Acetate Injection (Addl. Indication)	For use in following: (I) Empirical therapy for presumed fungal infections in febrile neutropenic patients (II) Treatment of Candidemia and the following Candida	31-1-2009

		infections: Intra-abdominal abscesses, Peritonitis and Pleural space infections. (III) Treatment of Esophageal Candidiasis. (IV) Treatment of invasive Aspergillosis in patients who are refractory to or intolerant of other therapies (i.e., amphotericin B, lipid formulations of amphotericin B, and/or itraconazole)	
13.	Micafungin (as sodium) Powder for solution for infusion 50 mg/vial	For the treatment of patients with candidemia, acute disseminated candidiasis, candida peritonitis, abscess and esophageal candidiasis. For the prophylaxis of Candida infection in patients undergoing hematopoietic stem cell transplantation (HSCT)	31-1-2009
14.	Loteprednol Etabonate Nasal spray 0.1% w/v	For prophylaxis and treatment of the nasal symptoms of seasonal allergic rhinitis	31-1-2009
15.	Rasagiline (as mesylate) Tablet 0.5 mg/1 mg	For the treatment of signs and symptoms of Idiopathic Parkinson's disease as initial monotherapy and as an addition to Levodopa	31-1-2009
16.	Nicotine Polacrilex Gum 2 mg & 4 mg (Addl. Indication)	To reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and guthka containing tobacco	3-2-2009
17.	Closantel Injection 100 mg/ml (for veterinary use)	For the infestation of trematodes, nematodes, cestodes and arthropods of domestic animals, including milch and other food producing animals	5-2-2009
18.	Lornoxicam 4 mg + Paraceta-mol 500 mg film coated tablets	For the short term use in acute painful & inflammatory conditions in adults	5-2-2009
19.	Cetrimide 15% w/v + Chlorhexidine Gluconate 7.5% v/v + Isopropyl Alcohol 7.5% v/v Concentrate Solution	For cleansing of physically contaminated wounds and for pre-operative disinfection	9-2-2009
20.	Ketoconazole 2% w/v + Prepared Coal Tar 2% w/v (I.P. 1966) Solution	For the treatment of dandruff	9-2-2009
21.	Doripenem (as monohydrate) Injection 250 mg/500 mg	For the treatment of nosocomial pneumonia in adults	16-2-2009
22.	Halobetasol Scalp Approved 0.05% w/v	For the relief of inflammatory and pruritic manifestation of corticosteroid responsive dermatosis	18-2-2009
23.	Nicotine (as Polacrilex) Lozenges 2 mg & 4 mg	To reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and guthka containing tobacco	18-2-2009
24.	Tranexamic Acid Tab SR 750 mg	For the treatment of menorrhagia	20-2-2009
25.	Bethahistine Mesilate Tablet 6 mg/12 mg	For the treatment of dizziness and feeling of dizziness resulting from Meniere's disease, Meniere's syndrome and vertigo	20-2-2009
26.	Abatacept Injection 250 mg/vial (Addl. Indication)	In moderately to severely active rheumatoid arthritis in adults and may be used as monotherapy or concomitantly with DMARD's other than TNF antagonists	20-2-2009
27.	Anidulafungin Injection (Lyophilized powder) 50 mg/ 100 mg per vial	For the treatment of invasive candidiasis including candidemia and esophageal candidiasis in adult patients	23-2-2009
28.	Hydroquinone 2%+ Tretinoin 0.05% + Hydrocortisone 1% Cream	For the treatment of patients with skin hyperpigmentation	23-2-2009
29.	Doxophylline 400 mg + Terbutaline 5 mg tablets	For the treatment of asthma and chronic obstructive pulmonary disease in adult patients only	23-2-2009
30.	Hydroquinone 20 mg + Tretinoin 0.25 mg + Fluocinolone Acetonide 0.1 mg per gm Cream	For the treatment of melasma of face in adults	23-2-2009

31.	Ketoconazole 2% + Zinc Pyrithone 1% Lotion	For the treatment of pityriasis and dandruff of the scalp	23-2-2009
32.	Lamivudine 30 mg + Zidovudine 60 mg + Nevirapine 50 mg Oral Suspension (Tablets for Oral Suspension)	For the treatment of HIV patients	23-2-2009
33.	Glibenclamide 5 mg + Pioglitazone 15 mg + Metformin 500 mg film coated tablets	As 3rd line treatment of Type II Diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control	23-2-2009
34.	Aceclofenac 100 mg + Tizanidine 2 mg film coated tablets	For the treatment of acute low back pain in adult patients only	23-2-2009
35.	Octinoxate 7.5% + Avobenzone 3% + Oxybenzone 3% + Titanium dioxide 2% lotion	As sunscreen lotion for prevention of sunburn skin	23-2-2009
36.	Cetirizine 5/10 mg + Ambroxol 30 mg per 5 ml syrup	For the symptomatic relief of productive cough associated with allergic rhinitis, when both anti-histamine and mucolytic agents are desired	23-2-2009
37.	Lidocaine Lozenges 200/300 mg	For single agent anesthesia in upper gastro intestinal endoscopy	26-2-2009
38.	Calamine 8% + Liquid Paraffin 10% lotion	As antipruritic and smoothening agent	26-2-2009
39.	Nifedipine 0.3% + Lidocaine 1.5% cream	For the treatment of anal fissures	26-2-2009
40.	Quinapril 20 mg + HCTZ 25 mg film coated tablet	For the treatment of mild to moderate hypertension in adult patients (in whom combination therapy is appropriate) who have been stabilized on the individual components given in the same proportion	26-2-2009
41.	Levodopa 100/100/250 + Carbidopa 10/25/25 mg mouth dissolving tablet	For the symptomatic symptoms of idiopathic Parkinson's Disease	4-3-2009
42.	Paliperidone ER Tablets 1.5 mg	Additional Strength	4-3-2009
43.	Losartan 100 mg+ HCTZ 25 mg tablet	Additional higher strength	16-3-2009
44.	Darunavir (as ethanolate) Tablet 300 mg	For the treatment of human immunodeficiency virus (HIV) infection in antiretroviral treatment experienced adult patients, such as those patients with HIV-1 strains resistant to more than one protease inhibitor when co-administered with 100 mg ritonavir, and with other antiretroviral agents	19-3-2009
45.	Ropivacaine HCl Inj. 2/5/7.5/10 mg	For the production of local or regional anesthesia for surgery and for acute pain management	19-3-2009
46.	Butaphosphan 100g + Methyl Hydroxybenzoate 1gm + Cyanocobalamin 50 gm Oral powder (Veterinary Drug)	As vitamin and phosphorous supplement for livestock, shrimp and fish	19-3-2009
47.	Fluticasone Furoate Nasal spray 27.5 mcg per spray	For the treatment of symptoms of allergic rhinitis	19-3-2009
48.	Octinoxate 7.5% + Avobenzone 2% + Oxybenzone 3% + Octocrylene 3%+ Zinc Oxide 2% lotion	A sunscreen lotion for prevention of sunburn skin	19-3-2009
49.	Omeprazole 20/40 mg + Sodium Bicarbonate 600 mg+ Magnesium Hydroxide 700 mg sachet	Additional Strength	19-3-2009
50.	Ambroxol 30 mg + Levo Salbutamol 1 mg+ Guiphenesin 50 mg /5 ml syrup	For the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis	19-3-2009
51.	Montelukast 4 mg+ Levocetirizine 2.5 mg tablet	Additional lower paediatric dose	19-3-2009
52.	Surgical Sealant	To be indicated for use in sealing suture lines along arterial and venous reconstructions	26-3-2009
53.	Lidocaine Patch 700 mg in aqueous base (50 mg per gram adhesive)	For the relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin	26-3-2009
54.	Bimatoprost Ophthalmic solution 0.03%	For the treatment of hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness	30-3-2009

55.	Trabectedin powder for concentrate for solution for infusion 1 mg/vial	For the treatment of patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents	30-3-2009
56.	Acebrophylline Syrup 10 mg/ml (Additional Indication)	For the treatment of children (age 6 to 12 years) with chronic obstructive pulmonary disease (COPD) and bronchial asthma	30-3-2009
57.	Mesalamine PR Tablets 1.2 gm	For the induction of remission in patients with active, mild to moderate ulcerative colitis	30-3-2009
58.	Mycophenolate Mofetil Tablets 750 mg Additional Strength	Same as approved	31-3-2009
59.	Ketorolac Tromethamine Gel 2% w/w	For the treatment of muscle, joint and post-traumatic stress	31-3-2009
60.	Theophylline 400 mg SR + Montelukast 10 mg Tablet	For the treatment of patients with bronchial asthma	31-3-2009
61.	Hyaluronic Acid Sodium Salt 0.2 gm + Silver Sulfadiazine 1.0 gm/25 gm tube Hyaluronic Acid Sodium Salt 50 mg + Silver Sulfadiazine 1.0 gm/100 gm gauze pads impregnated with cream	For the treatment of wound of different etiology	31-3-2009
62.	Telmisartan 80 mg + Amlodipine 5 mg tablet	Additional higher strength	31-3-2009
63.	Hyaluronic Acid Sodium Salt (i) Each 15 gm tube contains: Hyaluronic Acid Sodium Salt 0.2 gm/100 gm (ii) Sterile Gauze Pads impregnated with cream: Each gauze pad contains Hyaluronic Acid Sodium Salt 50/100 mg	For the treatment of wound of different etiology	31-3-2009
64.	Abatacept Injection 250 mg/vial (Additional indication)	For reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis/juvenile rheumatoid arthritis in pediatric patients 6 years of age and older who have had an inadequate response to one or more DMARD's such as MTX	10-4-2009
65.	Cetirizine 10 mg + Ambroxol 75 mg SR Tablet	For symptomatic relief of productive cough associated with allergic rhinitis, when both anti-histamine and mucolytic agents are desired	13-4-2009
66.	Ciclesonide 200 mcg + Formoterol 6 mcg + Tiotropium 9 mcg MDI	Indicated as third line treatment of severe cases of COPD, when monotherapy and second line therapy with two drugs do not respond adequately	13-4-2009
67.	Each film coated bilayered tablet contains: Metoprolol 25 mg/50 mg + Chlorthalidone 12.5 mg	For the treatment of patients with mild to moderate essential hypertension	13-4-2009
68.	Milnacipran 25/50 mg Caps (Addl. Indication)	For the management of fibromyalgia	15-4-2009
69.	Lornoxicam SR 16 mg Tabs	For the symptomatic treatment of pain and inflammation in patients of osteoarthritis & rheumatoid arthritis	25-4-2009
70.	Palonosetron HCl 0.075 mg IV Inj (Addl. Strength)	Same as approved	25-4-2009
71.	Each film coated bilayered tablet contains: Metoprolol 25 mg/50 mg + Chlorthalidone 6.25 mg/12.5 mg	Additional strength	25-4-2009
72.	Albendazole 400 mg + Ivermectin 6 mg tablet	For the treatment of intestinal helminthes and suppression of microfilaraemia especially with bancrofti infections	25-4-2009
73.	Decitabine Lyophilized powder for injection 50 mg/20 ml vial	For treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory	25-4-2009

		anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk international Prognostic Scoring System groups	
74.	Retapamulin Ointment 1%	For the topical treatment of bacterial skin and skin structure infections:— Primary impetigo, secondarily infected traumatic lesions, secondarily infected dermatoses	25-4-2009
75.	Each ml contains Calamine 15% w/v + Zinc Oxide 5% w/v + Bentonite 3% w/v+ Glycerin 5%w/v + Sodium Citrate 0.05 % w/v lotion	For the treatment of pruritis and prickly heat	8-5-2009
76.	Each 1000 ml of emulsion contains: Medium chain Triglycerides 100 gm + Soya oil 80 gm + Omega-3 Acid Triglycerides 20 gm + Egg Lecithin 12 gm + Glycerol 25 gm + Sodium Oleate 0.30 gm + Alpha-tocopherol 0.20 gm + Ascorbylpalmitate 0.30 gm + Sodium Hydroxide max. 0.06 gm + water for injection 784 gm emulsion for infusion	For the supply of fats, including essential Omega-6 fatty acids and Omega-3 fatty acids, as part of a parenteral nutrition regimen in adults if oral or enteral nutrition is impossible, inadequate or contraindicated	14-5-2009
77.	Sertaconazole Nitrate Powder 2% w/w & Lotion 2% w/v	For the topical treatment of the superficial fungal infections of the skin	2-5-2009
78.	Amlodipine Tablets 5 mg/10 mg (Additional Indication)	1. To reduce of fatal coronary heart disease and non-fatal myocardial infarction, and to reduce the risk of stroke. 2. To reduce the risk of coronary revascularization procedures and the need for hospitalization due to angina in patients with coronary artery disease	2-5-2009
79.	Clindamycin Phosphate Inj. 150 mg/ml & Clindamycin HCl Capsules 150 mg/300 mg (Additional Indication)	Prophylaxis of infection in neck and head surgery	2-5-2009
80.	Each 15 gm sachet contains: Lactulose 10 gm + Ispaghula husk 3.50 gm granules	For the treatment of chronic idiopathic constipation in adult patients only	16-5-2009
81.	Sucralose	For use as sweetner in drug formulations	9-5-2009
82.	Carvedilol Tablets 3.125/6.25/12.5/25 mg (Additional Indication)	To reduce cardiovascular mortality in clinically stable patients who have survived the acute phase of a myocardial infarction and have a left ventricular ejection fraction of $\leq 40\%$ (with or without symptomatic heart failure)	9-5-2009
83.	Dexketoprofen 12.5 mg/25 mg + Paracetamol 500 mg film coated tablets	For the treatment of Acute musculoskeletal pain	18-5-2009
84.	Pregabalin SR Tablet 150/300 mg	For the treatment of peripheral neuropathic pain in adults	16-5-2009
85.	Guaiphenesin ER Tablet 1200 mg	For the treatment of productive cough accompanied by Phlegm	16-5-2009
86.	Everolimus 5/10 mg Tablets (Addl. Indication)	Treatment of advance renal cell carcinoma	16-5-2009
87.	Nimesulide ER 200 mg (Additional Indication)	Acute pain in Orthopaedic, ENT, Dental and Post-Operative condition	16-5-2009
88.	Palonosetron Injection 0.25 mg/5 ml (Additional Indication)	For treatment of Post-Operative Nausea & vomiting	16-5-2009
89.	Bendamustine Hydrochloride Lyophilized powder Injection 100 mg/vial	For the treatment of patients with chronic lymphocytic leukemia	16-5-2009
90.	Caffeine (as Citrate) 10 mg/ml Injection	For the short term treatment of apnoea of prematurity of infants between 28 and < 33 weeks gestational age	16-5-2009
91.	Perindopril Arginine 2.5 mg/ 5 mg/10 mg film coated tablet	For the treatment of arterial hypertension, congestive heart failure and coronary artery disease	16-5-2009

92.	Each gm contains: Halobetasol 0.05% w/w + Mupirocin 2.0 % w/w gel	For the topical treatment of inflammatory dermatitis with secondary bacterial infection	16-5-2009
93.	Mometasone 0.1 % + Fusidic acid 2% cream/ointment	For the treatment of dermatoses where secondary bacterial and/or candidial infection is present	25-4-2009
94.	Thiocolchicoside 8 mg + Etoricoxib 60 mg tablets	Additional strength	25-4-2009
95.	Methadone Hydrochloride 5 mg/ 10 mg per ml syrup; 5 mg/10 mg/20 mg /40 mg tablet	For the treatment of opioid dependence and in maintenance treatment for opioid dependence	28-5-2009
96.	Trospium Chloride film coated tablet 20 mg	For the treatment of overactive bladder with the symptoms of urge urinary incontinence, urgency, and urinary frequency	28-5-2009
97.	Arformoterol (as Tartrate) 15 mcg /2 ml Inhalation Solution	For the long term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema	29-5-2009
98.	Zolmitriptan...5.0% w/v Benzalkonium Chloride NF0.01% w/v Nasal spray	For the acute treatment of migraine with or without aura in adults	29-5-2009
99.	Dexmedetomidine (as HCl) 100 mcg/ml Injection	For sedation of initially and mechanically ventilated patients during treatment in an intensive care setting	29-5-2009
100.	Levetiracetam SR Tablet 500/750/1000 mg	Same as approved	2-5-2009
101.	Glatiramer Acetate Injection (20 mg/ml) & Pre-filled syringe (20 mg/ml)	For the reduction of the frequency of relapses in patients with Relapsing-Remitting Multiple Sclerosis	3-6-2009
102.	Yttrium-90 Microspheres Injection (Yttrium-90...3GBq (at the time of calibration) per vial)	For the treatment of unresectable metastatic liver tumors from primary colorectal cancer with intra-hepatic artery chemotherapy (IHAC) of FUDR (Flouxuridine)	3-6-2009
103.	Luliconazole Cream 1%	For the treatment of cutaneous mycosis viz. Tinea pedis, Tinea corporis, Tinea cruris	3-6-2009
104.	Magnesium Valporate Prolonged release tablet 600 mg	(1) For the treatment of generalized or partial seizures as monotherapy or adjunctive therapy. (2) For prophylaxis of migraine headache in adults. (3) For the treatment of manic episodes associated with bipolar disorders	4-6-2009
105.	Tenofovir Disoproxil Fumerate 300 mg	For the treatment of chronic Hepatitis B in adults	19.6.2009
106.	Bosentan (as monohydrate) Tablets 62.5/125 mg	For the treatment of pulmonary arterial hypertension (WHO Group I) in patients with WHO Class III or IV symptoms, to improve exercise ability and decrease the rate of clinical worsening	23.6.2009
107.	Lornoxicam 12 mg SR (Additional Strength)	Same as approved	26.6.2009
108.	Azithromycin SR Granules for Oral Suspension 2000 mg	For the treatment for mild to moderate susceptible infection including RTI, uncomplicated skin/skin structure, non-gonococcal urethritis, cervicitis	26.6.2009
109.	Metoprolol 50/50/25 mg + Atorvastatin 20/10/10 mg + Ramipril 10/5/2.5 mg capsules	As 2nd line treatment of patients with both essential hypertension and hypercholesterolemia who are not adequately controlled by combination of an anti-hypertensive with lipid lowering agent	1-7-2009
110.	Methyl Phenidate ER Tablet 10/20/30 mg	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD)	10-7-2009
111.	Dasatinib Tablets 100 mg (Addl. Strength)	Same as approved	10-7-2009
112.	Voglibose 0.2 mg + Metformin 500 mg Tablets	As 2nd line treatment of Type II Diabetes mellitus when diet, exercise and the single agent do not result in adequate glycemic control	13-7-2009

113.	Combipack of Artesunate tablet and FDC Tablet of Sulphadoxine + Pyrimethamine Composition: A. Combipack of 1 strip of 3 tablets of artesunate 25 mg and 1 strip of 1 tablet of sulphadoxine 125 mg + pyrimethamine 6.25 mg B. Combipack of 1 strip of 3 tablets of artesunate 50 mg and 1 strip of 1 tablet of sulphadoxine 500 mg + pyrimethamine 25 mg C. Combipack of 1 strip of 3 tablets of artesunate 100 mg and 1 strip of 1 tablet of sulphadoxine 500 mg + pyrimethamine 25 mg D. Combipack of 1 strip of 3 tablets of artesunate 200 mg and 1 strip of 1 tablet of sulphadoxine 500 mg + pyrimethamine 25 mg	For the treatment of P. falciparum resistant malaria patients	15-7-2009
114.	Milnacipran 100 mg (Additional Strength)	Same as approved	16-7-2009
115.	Rifaximin 400 mg (Additional Indication)	For the treatment of hepatic encephalopathy	18-7-2009
116.	Nevirapine tablet 50 mg for oral suspension mg	For the treatment of HIV infection in combination with other anti-retro viral agents	18-7-2009
117.	Desvenlafaxine (as Succinate) ER Tablets 50 mg/100 mg	For the treatment of major depressive disorder (MDD)	18-7-2009
118.	Posaconazole Oral Suspension 40 mg/ml	For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole. For prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy	18-7-2009
119.	Caffeine Citrate 20 mg /ml (equivalent to 10 mg of Caffeine base) Oral Solution (Addl. Dosage form)	Same as approved	18-7-2009
120.	Amphotericin B Emulsion 5 mg/ml (Addl. Indication)	Febrile Neutropenia in cancer patients	18-7-2009
121.	Hydroxyethyl starch 10% solution for infusion	For the treatment of imminent or manifest hypovolemia and shock	18-7-2009
122.	Naratriptan (as HCl) Tablets 1/2.5 mg	For the acute treatment of migraine with or without aura in adults	18-7-2009
123.	Colistimethate Sodium powder for solution for injection/infusion 500000IU and 2000000 IU (Additional Strength)	Same as approved	20-7-2009
124.	Simvastatin 20 mg + Ramipril 5 mg + Atenolol 50 mg + HCTZ 12.5 mg + Aspirin 100 mg (EC Pellets) Capsules	For secondary prevention of coronary heart disease/stroke in patients where use of such combination is appropriate	21-7-2009
125.	Colistimethate Sodium powder for solution for inhalation 500000IU/1000000IU/2000000IU	Treatment by inhalation of Pseudomonas aeruginosa lung infection in patients with cystic fibrosis	28-7-2009
126.	Ramipril MR capsule 10 mg	For the treatment of hypertension/ cardiac failure and myocardial infarction	30-7-2009
127.	Abacavir Sulfate Tablet 60 mg	For the treatment of HIV-1 infection in combination with other antiretroviral agents	1-8-2009
128.	Zoledronic Acid Solution for Infusion (Addl. Indication)	Prevention of clinical fractures after hip fracture in men and women	1-8-2009
129.	Sumatriptan 85 mg + Naproxen 500 mg Tablets	Additional strength for the treatment of migraine	3-8-2009
130.	Aceclofenac (100 mg) + Thiocolchicoside (8 mg) tablets	For the treatment of acute inflammation conditions associated with spasm in adults only	3-8-2009
131.	Oxcarbazepine 150/300/600 mg Tablet (Addl. Indication)	Treatment of generalized tonic-clonic seizures in adults and children	13-8-2009

132.	Ofloxacin 2 mg + Ornidazole 5 mg per ml Infusion	For the treatment of diarrhoea of mixed infection in adult patients	17-8-2009
133.	Clozapine Tablet 200 mg (Addl. Strength)	Indicated in the management of Schizophrenic patients	19-8-2009
134.	Oxymetazoline Hydrochloride Nasal Spray 50 mcg/0.05%w/w	Is indicated for the relief of stuffy, running nose associated with colds and influenza, also post nasal drip, sinusitis	19-8-2009
135.	Enoxaparin Sodium Injection (Addl. Indication)	Treatment of acute ST-segment elevation myocardial infarction including patients to be managed medically or with subsequent percutaneous coronary intervention (PCI)	19-8-2009
136.	Fluvoxamine Maleate 100/150 mg ER Tablets	For the treatment of obsessive compulsive disorder (OCD) and depression	19-8-2009
137.	Lidocaine Lozenges 200/300 mg (Addl. Indication)	For single agent anesthesia in procedure involving the introduction of instrument & tubes into respiratory tract	19-8-2009
138.	Risperidone long acting injection (Addl. Indication)	Indicated as monotherapy or as adjunctive therapy in lithium or valproate for the maintenance treatment of Bipolar-I disorder	29-8-2009
139.	Exemestane 25 mg Tablet (Addl. Indication)	Indicated for adjuvant treatment of Post Menopausal Women with estrogen receptor positive early breast cancer who have received two-three year of tamoxifen and are switched to exemestane for completion of total of five years of adjuvant hormonal therapy	29-8-2009
140.	Artesunate (25/50/100 mg) + Amodiaquine (67.5 mg/135/270 mg) bilayerd Tablets	For the treatment of uncomplicated malaria due to plasmodium falciparum strain in various age groups	1-9-2009
141.	Ezetimibe 10 mg + Fenofibrate 145 mg film coated tablets	For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function	1-9-2009
142.	Buprenorphine Transdermal Patch each Transdermal Patch having an area of 6.25cm ² , 12.5cm ² , and 25cm ² contains: Buprenorphine...5 mg/10 mg/20 mg having release rate of 5 mcg, 10 mcg, 20 mcg Buprenorphine per hour respectively (over a period of 7 days).	For the treatment of severe opioid responsive pain conditions which are not adequately responding to non-opioid analgesics. For Hospital supply only	3-9-2009
143.	Trospium Chloride ER Capsules 60 mg	For the treatment of overactive bladder with the symptoms of urge urinary incontinence, urgency and urinary frequency	4-9-2009
144.	Metoclopramide (as HCl) 200 mg/400 mg per ml Intranasal Solution	For the treatment of nausea and vomiting	9-9-2009
145.	Isosorbide 20 mg + Hydralazine 37.5 mg tablets	For the treatment of heart failure as an adjunct to standard therapy in patients to improve survival, to prolong time to hospitalization for heart failure and to improve patients reported functional status	18-9-2009
146.	Cefixime 200 mg + Dicloxacillin ER 500 mg Tablets	For the treatment of adult patients with Upper and Lower respiratory tract infections, skin and soft tissue infections	22-9-2009
147.	Chlorthalidone Tablet 6.25 mg	For the treatment of mild to moderate hypertension	3-10-2009
148.	Cefovecin (as sodium) 80 mg/ ml Lyophilised powder for injection (Veterinary)	For the treatment of skin bacterial infections in dogs and cats	3-10-2009
149.	Imidacloprid 10% + Moxidectin 1.0% & 2.5% Topical solution (Veterinary) each pipette contains: (a) 0.4 ml, 1.0 ml, 2.5 ml, 4 ml of 10% Imidacloprid and 1.0% moxidectin (b) 0.4 ml, 0.8 ml of 10% Imidacloprid and 2.5% moxidectin	For the treatment and prevention of flea infestations, prevention of heartworm disease and treatment of infections with gastrointestinal nematodes in dogs and cats	3-10-2009

150.	Isoflupredone Acetate Suspension for Injection (2 mg per ml) (For Veterinary)	For the glucocorticoid, anti-inflammatory or supportive therapy to cattle suffering from conditions such as: (1) Overwhelming infections with severe toxicity (2) Bovine ketosis (3) Musculoskeletal conditions (4) Shock (5) Parturient paresis (supportive stress therapy for milk fever)	3-10-2009
151.	Saxagliptin (as HCl) 2.5 mg/5 mg Tablets	As an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes mellitus. (It should not be used for the treatment of Type 1 Diabetes mellitus or Diabetic ketoacidosis, as it would not be effective in these settings)	24-10-2009
152.	Calcipotriol Gel 0.005% (Additional dosage form)	For the treatment of moderate plaque psoriasis in adults	3-10-2009
153.	Lamotrigine MR Tablets 150 mg (Addl. strength)	Same as approved	3-10-2009
154.	Metoprolol Tartrate ER Tablet 75 mg (Additional strength)	Same as approved	3-10-2009
155.	Valganciclovir Powder for Oral Solution 50 mg/ml	For the treatment of cytomegalovirus (CMV) retinitis in AIDS patients and for prevention of CMV disease in solid organ transplant patients at high risk	9-10-2009
156.	Dexketoprofen Trometamol Gel 12.5 mg/gm	For the painful and inflammatory conditions associated with joints, tendons, ligaments and muscle	13-10-2009
157.	Donepezil Hydrochloride Orodispersible Tablet 5 mg/10 mg	For the treatment of mild to moderate severe Alzheimer's Dementia	15-10-2009
158.	Dexketoprofen Trometamol Injection 50 mg/2 ml	Symptomatic treatment of acute pain of moderate to severe intensity, when oral administration is not appropriate such as post-operative pain, renal colic and low back pain	22-10-2009
159.	Bromocriptine Mesylate Tablet IP 0.8 mg (Additional Indication)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes mellitus	22-10-2009
160.	Levosulpride ER Tablet 100/ 150/200 mg	For the treatment of depression and schizophrenia in adults	27-10-2009
161.	Ambroxol 30 mg + Terbutaline 2.5 mg + Guaiphenesin 100 mg + Menthol 2.5 mg per 5 ml syrup	Additional strength	27-10-2009
162.	Propofol 10 mg + Lignocaine 2.5 mg per ml injection	Additional strength	27-10-2009
163.	Mecobalamin 750 mg + Pyri-doxine Hydrochloride 1.5 mg + Nicotinamide 45 mg tablets	For the treatment of Diabetic neuropathy	27-10-2009
164.	Oltmesartan (20/40 mg) + Atorvastatin 5/10/20 mg film coated tablets	For the treatment of co-existing essential hypertension and hyperlipidemia in adult patients	27-10-2009
165.	Deltamethrin (0.50% m/v) and Piperonyl Butoxide (2.0% m/v) per ml Pour-On Solution	Ready to use pour-on for cattle, sheep and goats. 1. For use in cattle to control ticks, stable flies, horn flies, cattle louse flies and nuisance flies e.g. house flies, to kill lice and protection against blackflies 2. For use in sheep and goats for controlling Karoo paralysis, bont- legged and red-legged ticks	29-10-2009
166.	Glucosamine sulphate potassium chloride 500 mg + Ibuprofen IP 200 mg film coated Tablets	For the treatment of adult patients with osteoarthritis of knee and/or hip joints	3-11-2009
167.	Methylcobalamin 1500 mcg + Gabapentin SR 600 mg film coated tablets	Additional strength	4-11-2009

168.	Propofol 1% for injection (Additional Indication)	1. For conscious sedation for surgical and diagnostic procedures 2. For sedation of ventilated patients receiving intensive care	5-11-2009
169.	Rupatadine 10 mg + Montelukast 10 mg Tablets	For the management of seasonal allergic rhinitis (SAR)	10-11-2009
170.	Eperisone 50 mg + Paracetamol 500 mg Tablets	For improvement of myotonic conditions caused by neck shoulder arm syndrome, scapulohumeral periarthritis and low back pain in adult patients only	10-11-2009
171.	Lafutidine Tablets.....5 mg/10 mg	For the treatment of: • Gastric ulcers, duodenal ulcers and stromal ulcers • Gastric mucosal lesions (erosion, hemorrhage, redness or edema) associated with acute gastritis and acute exacerbation of chronic gastritis	11-11-2009
172.	Ramosetron Hydrochloride Tablets 2.5 mcg, 5 mcg, 0.1 mg & Injection 0.3 mg /2 ml	1. Tablets 0.1 mg & Injection 0.3 — for the prevention and treatment of gastrointestinal symptoms (nausea and vomiting) associated with emetogenic cancer chemotherapy. 2. Tablets 2.5 mcg & 5 mcg — for the treatment of diarrhoea predominant irritable bowel syndrome	11-11-2009
173.	Tadalafil tablet 20 mg (Additional Indication)	For the treatment of pulmonary arterial hypertension	14-11-2009
174.	Flurbiprofen Sodium 0.03% Ophthalmic solution USP	For the reduction of post-operative inflammatory condition	14-11-2009
175.	Dexmedetomidine HCl Injection (Additional Indication)	Sedation of non-intubated patients prior to and/or during surgical and other procedure	14-11-2009
176.	Paliperidone ER tablet 12 mg (Additional Strength)	Same as approved	14-11-2009
177.	(1) Triticum Vulgare Topical Cream each 100gm of cream contains: Aqueous extract of Triticum Vulgare (dry residue 200 mg/ 100 ml) 15 gm 2-phenoxyethanol Eur. Ph.... 1 gm (2) Triticum Vulgare Vaginal Pessary each 3.5 gm of vaginal pessary contains: Aqueous extract of Triticum Vulgare (dry residue 200 mg/ 100 ml) 0.60 gm 2-phenoxyethanol Eur. Ph..... 0.04 gm	(1) Triticum Vulgare Cream is indicated for the treatment of ulcers and bed sores. (2) Triticum Vulgare Vaginal Pessary is indicated for the treatment of phlogistic and dystrophic disorders of the female genital tract	14-11-2009
178.	Febuxostat Tablets 80 mg/120 mg	For treatment of chronic hyperuricemia in conditions where urate depression has already occurred (including a history, or presence of tophus and/or gouty arthritis)	14-11-2009
179.	Euphorbia Prostrata Dry Extract : 100 mg tablet (Addl. Indication)	For the treatment of 3° and 4° haemorrhoids (Addl. Indication)	14-11-2009
180.	Euphorbia Prostrata dry extract ethanolic 80%v/v [(35-70):1] cream 1% w/w	For the treatment of 1° and 2° internal haemorrhoids	14-11-2009
181.	Lactobacillus Rhammnosus 1 billion cells + Saccharomyces Boulardi 125 mg + Zinc Enriched yeast 20 mg sachets & capsules	For the treatment of acute diarrhoea in children	4-11-2009
182.	Nimesulide 1.0% w/w + Ethanol 31% w/w topical solution	For the local application in relieving pain in acute low backache, tendonitis, tenosinovitis and sprains	17-11-2009
183.	Diacerein Modified Release Capsule 100 mg	Symptomatic treatment of osteoarthritis of knee & hip	20-11-2009
184.	Amlodipine 5 mg/10 mg/5 mg/ 10 mg/10 mg + Valsartan 160 mg/160 mg/160 mg/160 mg/320 mg + Hydrochlorothizide 12.5 mg/12.5 mg/25 mg/25 mg/25 mg Tablets	For the treatment of essential hypertension	24-11-2009

185.	Maraviroc Tablets 150 mg/300 mg	For the treatment of patients infected with CCR 5-trophic HIV-1	25-11-2009
186.	S (+) Etodolac 150/200/300 mg + Paracetamol 500/500/500 mg Tablets	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis	25-11-2009
187.	Tacrolimus Granules for oral suspension 0.2/1 mg per sachet	Prophylaxis of transplant rejection in kidney, liver or heart allograft recipient	26-11-2009
188.	Rifaximin Dispersible Tablet 200 mg	For infections diarrhoea in adults	26-11-2009
189.	Prednisolone Sodium Phosphate Orally Disintegrating Tablet 10/ 15/30 mg	Indicating for condition required Glucocorticoids activity including collagen disease, allergic disease and hypersensitive reaction	26-11-2009
190.	Cinitapride Hydrogen Tartrate ER Tablet 3 mg	For the treatment of gastroesophageal reflux disease (GERD) and functional inconveniences of the gastrointestinal motility	26-11-2009
191.	Sevelamer Carbonate (Additional Indication)	For control of serum phosphorus in patients with chronic kidney disease on haemodialysis or peritoneal dialysis and patients with CKD not on dialysis with serum phosphate > 5.5 mg/dl	26-11-2009
192.	Oxcarbazepine Tablets (Additional Indication) 150/300/600 mg	Monotherapy in the treatment of partial seizures in children ages 4-16	26-11-2009
193.	Ketoprofen plaster 30 mg (7cm X 10 cm)	For the relief of musculoskeletal pain & inflammation	11-12-2009
194.	Acipimox Capsules 250 mg	As adjunctive therapy to diet and weight loss in the treatment of Type II-a, II-b and IV lipid disorders	26-11-2009
195.	Amisulpiride SR Tablet 100 mg	Same as approved	27-11-2009
196.	Mycophenolate Sodium Enteric coated tablet 540 mg (Additional Strength)	Same as approved	29-10-2009
197.	Loteprednol etabonate 0.5% w/v + Moxifloxacin 0.5% w/v ophthalmic Suspension	For the treatment of post operative steroid responsive inflammatory ocular infections or risk of bacterial ocular infections exists	1-12-2009
198.	Ropinirole ER tablet 2/4/8 mg	For the treatment of signs & symptoms of idiopathic Parkinson's disease	3-12-2009
199.	Diclofenac Diethyl amine transdermal patch 100 mg/37.5 sq cm (Additional Strength)	Same as approved	4-12-2009
200.	Lornoxicam ER Tablet 8 mg (Additional Strength)	Same as approved	11-12-2009
201.	Flurbiprofen plaster 20 mg (7 cm x 10 cm)	For the relief of pain & inflammation due to rheumatoid arthritis, osteoarthritis and allied disorder	11-12-2009
202.	Carvedilol Phosphate ER tablet 10/20/40/80 mg	1. Mild to severe chronic heart failure. 2. Left ventricular dysfunction following myocardial infarction in clinically stable patients. 3. hypertension	11-12-2009
203.	Halometasone monohydrate 0.05% w/w + Fusidic acid 2.00% w/w cream	For the treatment of acute and chronic infected eczematous dermatitis	15-12-2009
204.	Glimepiride 1/2 mg + Metformin 500 mg + Atorvastatin 10 mg tablets	For the treatment of type II diabetes mellitus associated with dyslipidemia	17-12-2009
205.	Bethahistine Di hydrochloride CR capsule 24/32/48 mg	Indicated in the treatment of Menier's syndrome, characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss	17-12-2009
206.	Gefitinib tab 250 mg (Additional Indication)	Indicated for the first line treatment of patients with locally advanced or metastatic non small cell lung cancer (NSLC) who have activating mutation of the EGFR TK	18-12-2009

207.	Midazolam HCl Syrup 2 mg/ml	For selection, anxiolysis and amnesia prior to diagnostic, therapeutic or endoscopic procedure or before induction of anesthesia	18-12-2009
208.	Guaiphenasin Syrup 133 mg/5 ml	For the treatment of productive cough accompanied by phlegm	18-12-2009
209.	Balofloxacin Tablet 100 mg	For the treatment of uncomplicated urinary tract infections (such as cystitis and urethritis)	22-12-2009
210.	Xylometazoline 0.5 mg + Ipratropium 0.6 mg Nasal spray	For symptomatic treatment of nasal congestion with running nose (rhinorrhea)	23-12-2009
211.	Doxofylline 400 mg + Ambroxol 30 mg Tablets	For the treatment of patients with bronchial asthma and COPD, when use of both the drug is appropriate	23-12-2009
212.	Ribavirin Capsules 200 mg (Addl. Strength)	Indicated in combination with peg interferon alpha-2b for the treatment of naïve adult patients with chronic Hepatitis C with clinically stable HIV co-infection	24-12-2009
213.	Formoterol 6 mcg + Mometasone furoate 100/200/400 mcg Metered dose Inhaler & Dry Powder Inhalation	For the treatment of patients with bronchial asthma and COPD, where the use of combination is found appropriate	30-12-2009
214.	Chlorohexidine Gluconate Gel 0.2%	For the prevention of Plaque and treatment of gingivitis	30-12-2009
215.	Chlorohexidine Gluconate Mouth wash 0.1%	For the prevention of Plaque and treatment of gingivitis	30-12-2009

List of Drugs approved during January to December, 2010

Sl. No.	Product Name	Indication	Date of Approval
1.	Ferrous ascorbate 100 mg + Folic acid 1.1 mg tablet and Omega-3-fatty acid 200 mg capsules combikit	For iron, folic acid & omega-3-fatty acid deficiency	8-1-2010
2.	Sphaeranthus Indicus extract Tablets 700 mg	For the management of psoriasis	8-1-2010
3.	Febuxostat 40 mg (Additional Strength)	Same as approved	16-1-2010
4.	Dexamethasone Intravitreal Implant 0.7 mg (In solid polymer drug delivery system)	For the treatment of macular edema following branch retinal vein occlusion (CRVO)	16-1-2010
5.	Bucizine HCl 25 mg Tablet (Additional Indication)	For the Symptomatic treatment of various allergic conditions (rhinitis, conjunctivitis and urticaria) and for prevention and treatment of motion sickness	16-1-2010
6.	Pemetrexed Disodium 500 mg/ 100 mg Powder for Injection (Additional indication)	Indicated as a monotherapy for the maintenance treatment of locally advanced or metastatic Non Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First line treatment should be a platinum doublet with gemcitabine, paclitaxel or docetaxel	16-1-2010
7.	Levobetaxolol HCl Ophthalmic Suspension 0.5%	For lowering of intraocular pressure in patients with chronic open-angle glaucoma or ocular hypertension	16-1-2010
8.	Sarpogrelate Hydrochloride film coated Tablets 100 mg	For the improvement of ischemic symptoms including ulcer, associated with chronic arterial occlusion	16-1-2010
9.	Propanolol 1-ol 18 gm + Ethanol 100% 45 gm/100 ml solution	For hygienic and surgical hand disinfection	18-1-2010
10.	Aliskiren 150/160 mg + Valsartan 300/320 mg tablets	For the treatment of hypertension	19-1-2010
11.	Piroxicam 20 mg tab & Paracetamol 500 mg tab combikit	For treatment of fever and pain associated with acute upper respiratory tract inflammation, acute musculoskeletal disorders, pain after operative intervention and following trauma, chronic condition like rheumatoid arthritis, osteoarthritis etc for short term management of acute painful episodes	19-1-2010

12.	Soybean oil 60 gm + Triglycerides (medium chain) 50 gm + olive oil purified fish oil 30 gm + dl-alpha-tocopherol 163-225 mg + glycerol (anhydrous) 25 gm + Egg lecithin 12 gm + sodium hydroxide (to approx pH 8) + sodium pleate 0.3 mg emulsion for infusion in 100 ml	Total parenteral nutrition following major abdominal, major thoracic or major urological surgery	19-1-2010
13.	Raltegravir (as Potassium) film coated Tablets 400 mg	In combination with other anti-retroviral agents for the treatment of human immunodeficiency virus (HIV-1) infection in treatment experienced patients with evidence of HIV-1 replication despite ongoing retroviral therapy	27-1-2010
14.	Deflazacort Tablet 18 mg (Additional Strength)	Same as approved	30-1-2010
15.	Pregabalin SR Tablet 75 mg (Additional Strength)	Same as approved	30-1-2010
16.	Rivaroxaban film coated Tablets 10 mg	For the prevention of venous thromboembolism in patients (VTE) in adult patients undergoing hip or knee replacement surgery.	30-1-2010
17.	Cinnarizine 20 mg + Dimenhydrinate 40 mg tablets	For the treatment of vertigo	3-2-2010
18.	Lipid based Amphotericin-B Gel 0.1%	Indicated in the treatment of cutaneous and mucocutaneous mycotic infections caused by candida (Monilia) species	5-2-2010
19.	Sodium Hyaluronate Injectable Gel 14 mg/ml, 18 mg/ml, 25.5 mg/ml (Additional Strength)	Same as approved	6-2-2010
20.	Milnacipran HCl 12.5mg (Additional Strength)	Same as approved	6-2-2010
21.	Ropinirole 6mg ER Tablets (Additional Strength)	Same as approved	6-2-2010
22.	Coseal Surgical Sealent 2/4/8 ml (Additional Indication)	(1) Enforcement of suture and staple lines in lung resection procedures. (2) Patients undergoing cardiac surgery to prevent or reduce the incidence, severity and extend of post-surgical adhesion formation. (3) Patients undergoing laparotomy or laproscopic abdomino-pelvic surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post-surgical adhesion formation	6-2-2010
23.	Pregabalin SR 75/150/300 mg + Methylcobalamin 1500 mcg tablets	For the treatment of adult patients with peripheral neuropathy	9-2-2010
24.	Ivabradine HCl Tablets 5/7.5 mg (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 > 60 bpm	10-2-2010
25.	Paracetamol Solution for Infusion (10mg/ml) in 50ml (Additional Packsize)	Same as approved	10-2-2010
26.	Ketorolac Tromethamine Ophthalmic Solution 0.45%	Indicated for the treatment of pain and inflammation following cataract surgery	10-2-2010
27.	Cytarabine Injection 100 mg Additional Packsize (20 ml)	In combination with other approved anti-cancer drugs is indicated for remission induction in acute non-lymphocytic leukemia of adults and children. It has also been found useful in the treatment of acute lymphocytic leukemia and the blast phase of chronic myelocytic leukemia. Intrathecal administration of cytarabine is indicated in the prophylaxis and treatment of meningeal leukemia	10-2-2010
28.	Olopatadine HCl Nasal Spray 0.6% w/w (Additional Indication)	For the relief of the symptoms of seasonal allergic rhinitis in patients 6 years of age and older	10-2-2010

29.	Sodium chloride 6.80 gm + Potassium chloride 0.30 gm + Calcium chloride dihydrate 0.37gm + Magnesium chloride hexahydrate 0.20 gm + Sodium acetate trihydrate 3.27 gm + L-malic acid 0.67 gm in 1000 ml solution for infusion	Replacement of extracellular fluid losses in case of isotonic dehydration, especially if acidosis is being imminent or present	11-2-2010
30.	Chemically Modified Sodium Hyaluronate and Caboxymethylcellulose Absorbable Adhesion Barrier	As an adjunct in abdominal or pelvic surgery for reducing the incidence, extent and severity of post-operative adhesions at the site of placement	11-2-2010
31.	Lornoxicam 4 mg/4 mg + Thiocolchicoside 4 mg/8 mg tablets	For the treatment of patients with acute painful musculoskeletal conditions	12-2-2010
32.	Cefixime 100 mg/200 mg + Cloxacillin 500 mg/500 mg tablets	For the treatment of adult patients with upper & lower respiratory tract infections, skin and soft tissue infections	12-2-2010
33.	Celecoxib Mouth Dissolving Tablet 50/100/200 mg	For the treatment of Osteoarthritis and Rheumatoid Arthritis	25-2-2010
34.	Propofol 2% w/v Injection (Additional Strength)	Same as Approved	27-2-2010
35.	Spirolactone 25mg + Furosemide 20mg tablets	For treatment of resistant oedema associated with secondary hyperaldosteronism; resistant hypertension, chronic cardiac failure and hepatic cirrhosis	5-3-2010
36.	Olopatadine 5mg + Ambroxol 30mg tablets	For the management of cough in adult patients only	5-3-2010
37.	Methylcobalamin 750mcg + Pregabalin 75/150mg + Vitamin B 61.5mg + Folic Acid 0.75mg + Benfotiamine 7.5mg capsules	For the treatment of painful diabetic neuropathy in adults only	5-3-2010
38.	Calcium Acetate 435mg + Magnesium Carbonate 235mg tablets	For the management of hyperphosphatemia in adult patients with renal failure being treated with dialysis (hemodialysis or peritoneal dialysis)	5-3-2010
39.	Dicyclomine 2.5mg + Dried Aluminium Hydroxide 200mg + Light Magnesium Oxide 100mg + Simethicone 20mg per 5ml suspension	For the treatment of the symptoms of functional gastrointestinal disorders like irritable bowel syndrome, functional dyspepsia, peptic ulcers, GERD which includes smooth muscle spasm, flatulence, abdominal distension, hyperacidity, gastric distress, bloating etc.	5-3-2010
40.	Sertaconazole 2% w/v + Zinc Pyrithione 1% w/v Shampoo	For the treatment in adult patients with dandruff/seborrheic dermatitis of the scalp	5-3-2010
41.	Faropenam Sodium Extended Release Tablet 225/300/450 mg	For the treatment of respiratory tract infections, urinary tract infection, skin and skin structure infections and gynaecological infections	8-3-2010
42.	Amlodipine 5mg + Ramipril 10mg/5mg Tablets (Additional Strength)	For the treatment of hypertension only	10-3-2010
43.	Doxofylline MR Tablet 650 mg	For the treatment of Bronchial Asthma and COPD in Adults	11-3-2010
44.	Lidocaine 7.5mg + Prilocaine 2.5mg per actuation spray	For the treatment of adult male patients with premature ejaculation	12-3-2010
45.	Pramipexole Di HCl Monohydrate ER Tablet 0.375/0.75/1.5/3/4.5 mg	For the treatment of the sign and symptoms of Idiopathic Parkinsons disease	13-3-2010
46.	Drospirenone 3mg + Ethinyl Estradiol 0.02mg tablets	For the treatment of symptoms of premenstrual dysphoric disorders (PMDD) in women (Additional Indication)	16-3-2010
47.	Miglitol 25 mg + Metformin 500 mg tablets	Additional Strength	16-3-2010
48.	Propranolol 40mg (SR Pellets) + Flunarizine 5mg/10mg capsules	For the prophylaxis of migraine	16-3-2010
49.	Citicholine 500mg + Piracetam 400mg tablets	For the treatment of acute stroke	16-3-2010
50.	Diclofenac 50mg + Chlorzoxazone 500mg tablets	For the treatment of acute inflammation conditions associated with spasm in adults only	16-3-2010

51.	Mecobalamin 750 mcg + Pyridoxine 1.5 mg + Nicotinamide 45 mg + Benfotiamine 150 mg tablets	For the treatment of diabetic neuropathy in adults	16-3-2010
52.	Etoricoxib 1%+Menthol 5% Spray	For the topical treatment of acute musculoskeletal pain	16-3-2010
53.	Pantoprazole 40mg + Cinitapride (ER) 3mg capsules	For the treatment of patients suffering from non-ulcer dyspepsia (NUD) or gastroesophageal reflux disease (GERD)	17-3-2010
54.	Atorvastatin 20mg + Ramipril 2.5mg/5mg capsules	Additional higher strength	17-3-2010
55.	Lamotrigine Orodispersible Tablet 12.5 mg (Additional Strength)	Same as Approved	20-3-2010
56.	Trabectedin powder for conc. solution for infusion (Additional Indication)	In combination with pegylated liposomal doxorubicin, it is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer	20-3-2010
57.	Lomoxicam 8mg/8mg + Thiocolchicoside 4mg/8mg tablets	Additional higher strength	23-3-2010
58.	Diclofenac Sodium SR Tablet 150 mg	For the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, gout, painful post-operative pain following dental surgery etc.	26-3-2010
59.	Magnesium Valproate CR Tablet 200/ 300/400/ 500 mg (Additonal Strength)	Same as approved	26-3-2010
60.	Lidocaine 2.5% w/w+Prilocaine 2.5% w/w Gel	Additional higher strength	26-3-2010
61.	Nicotinic Acid and Laropiprant Modified Release Tablets: Nicotinic Acid.....1000 mg Laropiprant20mg	1. For the treatment of dyslipidaemia, particularly in patients with combined mixed dyslipidaemia (characterised by elevated levels of LDL-cholesterol and triglycerides and low HDL-cholesterol) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial). 2. In combination with HMG-CoA reductase inhibitors (statins), when cholesterol lowering effect of HMG-CoA reductase inhibitor monotherapy is inadequate. It can be used as monotherapy only in patients in whom HMG-CoA reductase inhibitors are considered inappropriate or not tolerated. Diet or other non-pharmacological treatments (e.g. exercise, weight reduction) should be continued during therapy.	26-3-2010
62.	Pantoprazole Mouth Dissolving Tablet 20/40 mg	For the treatment of gastric ulcer, duodenal ulcer & gastroesophageal reflux disease (GERD)	30-3-2010
63.	Praziquantel 175mg + Pyrantel 504mg + Febental 525mg Tablets	For the treatment of mixed infections with roundworms and tapeworms in dogs	30-3-2010
64.	Difluprednate Ophthalmic Emulsion 0.05% w/v	For the treatment of inflammation and pain associated with ocular surgery	30-3-2010
65.	Tolperisone HCl SR 450mg Tablets	For the relief of painful muscle spasms of the skeletal musculature	30-3-2010
66.	S(-)Metoprolol 25mg/50mg (ER) + Atorvastatin (IR)10mg tablets	For the treatment of patients with both essential hypertension and hypercholesterolemia	4-1-2010
67.	Atorvastatin10mg + Ramipril 5mg + Aspirin (EC pellets) 75mg/150mg + Metoprolol (ER tablets) 25mg Capsules	For secondary prophylaxis of ischemic heart disease in patients where use of such combinations in appropriate	5-4-2010
68.	Lamotrigine 25mg Modified Release Tablet (Additional Strength)	Same as approved	5-4-2010
69.	Imatinib Mesylate 100/400mg Tablets (Additional Indication)	Adjuvant treatment of adult patients following resection of gastro-intestinal stromal tumours (GIST)	5-4-2010

70.	Azithromycin SR Granules for Oral Suspension 1gm (Additional Strength)	Same as Approved	5-4-2010
71.	Gemfibrozil Capsule USP & Gemfibrozil Tablet USP 200mg/600mg (Additional Indication)	For the treatment of other dyslipidemias: (a) Fredrickson Types III and V (b) Associated with diabetes (c) Associated with xanthomata	5-4-2010
72.	Ibuprofen 400mg + Chlorzoxazone 500mg tablets	For the short term treatment of musculoskeletal pain associated with inflammation and spasm in adults only	7-4-2010
73.	Doxophylline (SR) 400mg/ 800mg + Montelukast 10mg/ 10mg Tablets	For the treatment of bronchial asthma in adults	7-4-2010
74.	Dronedarone(as Hydrochloride) film coated tablet.....400 mg.	To reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardio-vascular risk factors (i.e., age > 70, hypertension, diabetes, prior cerebro-vascular accident, left atrial diameter > 50mm or left ventricular ejection fraction [LVEF] < 40%), who are in sinus rhythm or who will be cardioverted.	8-4-2010
75.	Dosulepin HCl Tablet 25mg/ 75mg (Additional Indication)	For the treatment of chronic pain.	8-4-2010
76.	Prasugrel (as Hydrochloride) film coated tablet.... 5 mg/ 10mg	To reduce the rate of thrombotic cardiovascular (CV) events (including stent thrombosis) in patients with acute coronary syndrome (ACS) who are to be managed with percutaneous coronary intervention (PCI) as follows: • Patients with unstable Angina (UA) or non-ST-Elevation Myocardial Infarction (NSTEMI). • Patients with ST-Elevation Myocardial Infarction (STEMI) when managed with primary or delayed PCI.	13-4-2010
77.	Tofisopam uncoated tablet JP... 50/100mg	For the treatment of anxiety and depression.	13-4-2010
78.	Zotepine tablet 25/50/100mg	For the treatment of schizophrenia	15-4-2010
79.	Armodafinil uncoated tablet .. 50/150/250mg	To improve wakefulness in patients with excessive sleepiness associated with treated obstructive sleep apnea (OSA), shift work sleep disorder (SWD) or narcolepsy.	23-4-2010
80.	Indacaterol (as Maleate) Inhalation Powder Hard Capsules 150/300mcg	For maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).	24-4-2010
81.	Ranolazine ER Tablets 750mg (Additional Strength)	Same as Approved	24-4-2010
82.	Tacrolimus Capsules 3mg (Additional Strength)	Same as approved	24-4-2010
83.	Cefixime 100mg/200mg + Ofloxacin 100mg/200mg tablets	For the treatment of patients with typhoid fever and urinary tract infection in adults	26-4-2010
84.	Liquid paraffin 6% + White soft paraffin 15%w/v Cream	For symptomatic relief of dermatological condition associated with dry skin including atopic dermatitis, eczema, pruritus, ichthyosis, xerosis, psoriasis	29-4-2010
85.	Levosimendan Injection 2.5mg/ ml	For the short term treatment of acutely decompensated chronic heart failure (ADHF) in situations where conventional therapy is not sufficient and in cases where inotropic support is considered appropriate.	30-4-2010
86.	Thiocholchicoside SR Tablet 16 mg	As an adjuvant treatment in painful spasms associated with degenerative vertebral disorders and vertebral static problems, torticollis dorsal pain, low back pain, traumatological and neurological disorders.	31-4-2010

87.	Telmisartan 40/80 mg+ Indapamide SR 1.5/1.5 mg tablet	For the treatment essential hypertension	5-4-2010
88.	One strip of 3 uncoated tablets of artesunate 150mg & one strip of 2 uncoated tablets of FDC of Sulphadoxine IP 500mg + Pyrimethamine IP 25mg	Additional strength	5-4-2010
89.	Lapatinib Ditosylate Tablets 250mg (Additional Indication)	In combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.	10-5-2010
90.	Pentosan Polysulfate Sodium Capsules 100mg	For the relief of bladder pain or discomfort associated with interstitial cystitis.	11-5-2010
91.	Indapamide (SR) 1.5mg/1.5mg +Nebivolol 2.5mg/5mg tablet	For the treatment of hypertension not controlled with monotherapy	12-5-2010
92.	Cinitapride (ER) 3mg + Omeprazole (EC) 20mg Capsules	For the treatment of gastirc ulcer,gastroesophageal reflux disease(GERD) & Dyspepsia not responding to omeprazole alone	12-5-2010
93.	Timolol Maleate Long Acting Ophthalmic Solution 5mg/ml	For the treatment of elevated intraocular pressure in patient with ocular hypertension or open angle glaucoma.	14-5-2010
94.	Telmisartan tablet 20/40/80 mg(Additional Indication)	For the prevention of cardiovascular morbidity and mortality in patient 55 years older at high risk of cardiovascular disease	14-5-2010
95.	Dexketoprofen Trometamol 25mg + Thiocolchicoside 4mg tablets	For the treatment of acute low back pain and other musculoskeletal painful & inflammatory conditions in adult patients	20-5-2010
96.	Troxipide film coated Tablets 50mg /100mg	For the treatment of Gastric ulcers and for amelioration of gastric mucosal lesions (erosion, hemorrhage, redness and edema) in the diseases such as acute gastritis, acute exacerbation stage of chronic gastritis	20-5-2010
97.	Ambrisentan film coated Tablets 5 mg/10mg	For the treatment of pulmonary arterial hypertension (WHO Group I) in patients with WHO Class II or III symptoms to improve exercise capacity and delay clinical worsening	24-5-2010
98.	Rosuvastatin Calcium Tablet (Additional Indication)	Risk reduction of MI stroke and arterial evascularisation procedure in patients without clinically evident CHD but with multiple risk factor	24-5-2010
99.	Paracetamol SR 1000mg Bilayered tablet	For symptomatic treatment of pain and fever	24-5-2010
100.	Tacrolimus PR Caps 0.5/1/5 mg	For Prophylaxis of transplant rejection in adult kidney or liver allograft rejection	24-5-2010
101.	Rizatriptan Benzoate orally disintegrating tablet 10 mg(Additional Dosage Form)	Same as Already approved	24-5-2010
102.	Ramipril 1.25/2.5/5/10 mg (Additional Indication)	For the treatment of non-diabetic overt glomerular or incipient nephropathy	24-5-2010
103.	Exenatide Inj. (Additional Indication)	Use in patients with type-2 diabetes mellitus who are using a thiazolidinedione alone or in combination with metformilin but have not achieved adequate glycemic control	24-5-2010
104.	Temozolomide Lyophilised powder 100mg/vial	For the treatment of “Adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment.” Children from the age of three years, adolescents and Adult patients with malignant giloma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.	24-5-2010

105.	Fluticasone Propionate 50mcg/ 125mcg/250mcg + Salmeterol xinafoate 25mcg/25mcg/25mcg Powder for inhalation	For the maintenance treatment of asthma and for the treatment of COPD associated with chronic bronchitis	25-5-2010
106.	Cross linked Hyaluronic Acid 24mg + Lidocaine 3mg Pre-filled syringes	For filling any medium sized depression of the skin via mid dermis injection as well as for lip definition. The presence of lidocaine is meant to reduce the patients pain during the treatment	28-5-2010
107.	Aceclofenac 1% w/w + Menthol 5% Spray	For the treatment of acute painful inflammatory conditions in adults only	28-5-2010
108.	Metformin SR 500mg/500mg + GliclazideSR 60mg/30mg + Pioglitazone 15mg/15mg tablets	As 3rd line treatment of Type II diabetes mellitus when diet, exercise and the single agents and the second line therapy with two drugs do not result in adequate glycemic control	28-5-2010
109.	3 tablets of Artesunate 100mg + 3 tablets of Artesunate 50mg & 2 tablets of FDC of Pyrimethamine 25mg + Sulphadoxine 500mg combipack	Additional Strength	28-5-2010
110.	Calcium Carbonate 600 mg + Simethicone 80mg Chewable tablet	To relieve the uncomfortable symptoms of acid indigestion, heart burn, gas or sour stomach	28-5-2010
111.	Activated Dimethicone 50mg + Magnesium Hydroxide 250mg+ Dried Aluminium Hydroxide 250 mg + Sorbitol (70%) 1.25 gm/ 5ml Solution	For treatment of symptoms of hyperacidity (e.g. heartburn, epigastric discomfort, or their equivalents) that are often associated with dyspepsia, peptic ulcers, gastritis, peptic esophagitis and indicated for relief of flatulence	28-5-2010
112.	Aspirin 75mg + Simvastatin 10mg/20mg + Lisinopril 5mg/10mg + Atenolol 25mg/50mg tablets	For secondary prevention of coronary heart disease/stroke in patients where use of such combination is appropriate	1-6-2010
113.	Irsogladine Maleate Tablet 2mg/4mg	For gastric ulcers, improvement of gastric mucosal lesion (erosion, hemorrhage, redness and edema) caused by acute gastritis and acute exacerbation stage of chronic gastritis.	5-6-2010
114.	Lacosamide film coated tablet 50mg/100mg/150mg/200mg	As an adjunctive treatment of partial onset seizures in patients > 17 years of age.	10-6-2010
115.	Carmustine for inj. 100 mg	Indicated as palliative therapy as a single agent or in established combination therapy with other approved chemotherapeutic agents in the following: 1. Brain tumors—glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors. 2. Multiple myeloma—in combination with prednisone. 3. Hodgkin's Disease—as secondary therapy in combination with other approved drugs in patients who relapse while being treated with primary therapy, or who fail to respond to primary therapy. 4. Non-Hodgkin's lymphomas—as secondary therapy in combination with other approved drugs for patients who relapse while being treated with primary therapy, or who fail to respond to primary therapy.	10-6-2010
116.	Monteleukast Sodium Tablet 10mg; Monteleukast Sodium 4/5mg Chewable Tablet; Monteleukast Sodium Oral granule(Additional Indication)	For the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older.	12-6-2010
117.	Ramoteron Dispersible Tablet 0.1 mg	For the prevention and treatment of gastrointestinal symptoms (nausea and vomiting) associated with ematogenic cancer chemotherapy	12-6-2010
118.	Amitraz 2%w/v pour on solution	For the control of ticks on cattle and ostriches	12-6-2010

119.	Flupirtine Maleate Capsules 100mg	For treatment of acute and chronic pain, i.e, for painful increased muscle tone of the posture and motor muscles, primary headache, tumor pain, dysmenorrhea and pain after traumatologic/orthopaedic operations and injuries.	12-6-2010
120.	Lidocaine Patch 350mg (Additional Pack Size)	For the relief of pain associated with post-herpetic neuralgia. It should be applied only to intact skin.	17-6-2010
121.	Oseltamivir Phosphate (Additional Indication)	In the treatment of children 6 to 12 months of age during a pandemic influenza outbreak.	19-6-2010
122.	Methylcobalamin 1500 mcg + Folic Acid 0.7 mg+Niacinamide 12mg injection	For the treatment of diabetic neuropathy in adults	23-6-2010
123.	Methylcobalamin 1500mcg + Pyridoxine 100mg + Nicotinamide 100mg injection	For the treatment of diabetic neuropathy in adults	23-6-2010
124.	1 tablet of Tenofovir Disoproxil 300mg + Lamivudine 300mg & 2 tablet of Nevirapine 200mg combipack	For the treatment of HIV infection in adults	23-6-2010
125.	Vitamin A (oily form) as Palmiate 2000IU + Vitamin B1 1mg + Vitamin B2 1mg + Vitamin B6 1.34mg + Vitamin B12 1mcg + Ascorbic Acid 33.3mg + Vitamin D3 200IU + Folic Acid 0.3mg + Calcium Pantothenate 1mg + Niacinamide 15mg + Dibasic Calcium Phosphate 100mg + Phosphorus 77mg+ Ferrous Fumarate 50mg + Copper 0.01mg+ Potassium Iodide 0.0015mg + Heavy Magnesium Oxide 1mg + Manganese Sulphate 0.01mg + Potassium Sulphate 1mg + Zinc Sulphate 0.15mg Capsule	For the treatment of vitamin deficiency states in adults	23-6-2010
126.	Ramipril MR Capsules 2.5/5 mg (Additional Strength)	Same as Approved	3-7-2010
127.	Sitagliptin Phosphate 25/50/100 mg Tablet (Additional Indication)	(i) Use of Sitagliptin Phosphate in combination with Metformin and a PPAR γ agonist as an adjunct to diet & exercise in adult patients with Type-2 Diabetes mellitus who are inadequately controlled on combination therapy with Metformin and a PPAR γ agonist. (ii) Use of Sitagliptin Phosphate in combination with insulin, alone or in combination with Metformin.	3-7-2010
128.	Erlotinib HCl 25/100 mg Tablet (Additional Indication)	As monotherapy for maintenance treatment in patients with locally advanced or metastatic non-small cell lung cancer with stable disease after 4 cycles of standard platinum based first line chemotherapy.	3-7-2010
129.	Gemcitabine HCl injection 2gm/vial (Additional Strength)	Same as Approved	3-7-2010
130.	Etizolam 0.25 mg tablet (Additional Strength)	Same As Approved	3-7-2010
131.	Dexketoprofen 1.25% w/w + Linseed Oil 3.0%w/w +Menthol 5%w/w + Methyl Salicylate 10%w/w (12.5mg)	For the topical treatment of acute musculoskeletal pain	6-7-2010
132.	Cefuroxime Sodium 750/ 1500mg +Sulbactam Sodium 375/750mg	For the treatment of mild to moderate lower respiratory tract infection	6-7-2010
133.	HPMC 0.3% +Dextran 0.1% + Glycerin 0.2%	For the temporary relief of burning and irritation due to dryness of the eye and for use as a protection against further irritation. For the temporary relief of discomfort due to minor irritations of the eyes or to exposure to wind or sun	6-7-2010
134.	Cyanocobalamin 15mcg + Chromium Picolinate USP 250mcg + Folic Acid USP 1500 mcg+Nicotinamide IP100 mg + Pyridoxine 3mg +Selenius Acid USP 100mcg+Zinc Sulfate Monohydrate USP 61.8 mg eq. to 22.5 mg	For Mineral & Vitamins deficiency states in adult patients	6-7-2010

135.	Methylparaben 0.15%w/w + Propyl Paraben 0.05%w/w + Glycerin 20%w/w +CMC 1.74%w/w +Allantoin 0.5%w/w +Benzyl Alcohol 0.5%w/w.	For short term treatment of chronic wounds including Stage III & IV pressure sores, leg ulcers	6-7-2010
136.	Clonazepam IR 0.5mg/0.5mg+ Paroxetine CR 12.5/25mg	For the treatment of patients with co-morbid depression and anxiety	8-7-2010
137.	Nilotinib Capsules 200mg	For the treatment of chronic and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib.	10-7-2010
138.	Imipenem 50mg + Clistatin 50mg	Treatment of infection caused by susceptible bacteria for the following indication as in neonates and infants (below 3 months of age) 1. Lower respiratory tract infections 2. Urinary tract infections 3. Intra-abdominal infections 4. Bacterial septicaemia 5. Bone and joint infections 6. Skin and Skin structure infections 7. Bacterial endocarditis	14-7-2010
139.	Lidocaine Lozenges 100mg (Additional Strength)	Same as approved	15-7-2010
140.	Metoprolol Succinate ER 25/50 mg+Telmisartan 20/40mg	For the treatment of essential hypertension	16-7-2010
141.	Etodolac 300/300mg + Thiocolchicoside 4/8mg	For the treatment of patients with acute painful musculoskeletal conditions	19-7-2010
142.	Celecoxib 100/200mg + Diacerein 50/50mg	For the treatment of adult patients with osteoarthritis of knee and/or hip joints	19-7-2010
143.	Metoprolol succinate ER 25mg+ 50mg + Olmesartan 20/20mg	For the treatment of essential hypertension	19-7-2010
144.	1 tablet of Atazanavir 300mg & 1 tablet of Ritonavir 100mg & FDC of Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg (Each Co-pack contains:— 1 capsule of Atazanavir 300mg & 1 Tablet of Ritonavir 100mg & 1 Tablet of FDC of Tenofovir Disoproxil Fumarate 300mg + Lamivudine 300mg)	For the treatment of HIV infections in adults	19-7-2010
145.	Gliclazide 40/80mg+Metformin 500mg+Pioglitazone 15mg	Additional strength	19-7-2010
146.	Lidocaine HCl Ophthalmic Sterile Gel 35 mg/ml	Indicated for ocular surface anaesthesia during ophthalmologic procedures.	30-7-2010
147.	Naftopidil Tablets 25/50/75mg	For the treatment of dysuria associated with benign prostatic hyperplasia.	30-7-2010
148.	Metformin 500/850/1000mg+ Sitagliptin Phosphate 50/50/50 mg (Additional Indication)	(A) FDC is indicated as triple combination therapy with a PPAR γ agonist (i.e a thiazolidinedione) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of Metformin and a PPAR γ agonist. (B) FDC is also indicated as add-on to insulin (i.e triple combination therapy) as an adjunct to diet and exercise to improve glycemic control in patients when stable dosage of insulin and metformin alone do not provide adequate control	2-8-2010
149.	Bimatoprost Eye Drops 0.1mg/ ml	For the treatment of hypotrichosis of the eye-lashes by increasing their growth including length, thickness & darkness	5-8-2010
150.	S(+) Etodolac 5/10%w/w + Camphor 4%w/w + Menthol 10%w/w + Methyl Salicylate 5%w/w + Linseed oil 3%w/w	For the painful & inflammatory conditions associated with joint, tendons, ligaments and muscles	5-8-2010

151.	Cefpodoxime 100/200mg+ Dicloxacillin ER 500/500mg	For the treatment of lower RI, Skin and soft tissue, bone and joint infections and ENT infections in adult patients prone to antibiotic induced diarrhoea	6-8-2010
152.	Voglibose0.3 + Metformin (SR) 500mg	Additional higher strength	6-8-2010
153.	Amoxycillin Oral Suspension 200/400 mg per 5ml	In the treatment of infections due to susceptible strains of the designated micro-organisms in the condition of E.N.T infection, skin & skin structure infection, lower respiratory tract infection, genito-urinary tract infection, gonorrhea, acute uncomplicated (anogenital & urethral) infections	9-8-2010
154.	Olmesartan 40mg + Amlodipine 5mg (Additional Strength)	Additional indication: 1. For the treatment of hypertension alone or with other antihypertensive agents 2. To use as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals	9-8-2010
155.	Doripenem 500 mg powder for injection (Additional Indication)	Complicated intra-abdominal infections and complicated urinary tract infections, including complicated and uncomplicated pyelonephritis and cases with concurrent bacteremia	10-8-2010
156.	Nadolol tablet USP 20/40/80 mg	In the treatment of Angina-pectoris, Cardiac Arrhythmias & essential hypertension	20-8-2010
157.	Fluconazole for Oral Suspension 50/200 mg per 5ml (Pack Size : 35ml)	For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy	20-8-2010
158.	Metformin 500/500mg + Repaglinide 1/2mg	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes mellitus who are already treated with a Meglitinide & Metformin or who have inadequate glycemic control on a Meglitinide alone or Metformin	20-8-2010
159.	Hydroxyzine Hydrochloride SR Tablets 25/50/75mg	For management of pruritus due to allergic conditions such as chronic urticaria and atopic contact dermatoses, and in histamine - mediated pruritus	20-8-2010
160.	Rosuvastatin 5/10/20mg+ Fenofibrate 67/145/160mg	For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function	23-8-2010
161.	Fexofenadine 120mg+ Montelukast 10mg	For treatment of allergic rhinitis in adults only	31-8-2010
162.	Irinotecan HCl Trihydrate Injection 20 mg/ml (Pack Size 25ml)	For the treatment of metastatic colorectal cancer.	31-8-2010
163.	Cefixime SR 200mg/400mg + Ofloxacin SR 200mg/400mg Tablet	Additional strength	31-8-2010
164.	Ademetionine enteric coated Tablets200mg/400mg	For the management of intrahepatic cholestasis and liver disease	1-9-2010
165.	Memantine HCl ER Tablet 28mg	in the treatment of moderate to severe Alzheimer's disease.	6-9-2010
166.	Buserelin Acetate injection 1mg/ml (Additional Indication)	indicated for the palliative (initial & maintenance treatment) of patients with hormone-dependent advanced carcinoma of the Prostate gland (Stage D).	8-9-2010
167.	Etodolac 400mg/400mg + Thiocolchicoside 4mg/8mg tablet	Additional higher strength	9-9-2010
168.	Montelukast Sodium 10 mg Tablet, Montelukast Sodium 4/5 mg Chewable Tablet and Montelukast Sodium Oral Granules (Additional Indication)	For the relief of perennial allergic rhinitis in adults & pediatrics patients 6 months of age and older	11-9-2010

169.	Acyclovir SR Tablet 1200 mg	For the treatment of uncomplicated Herpes Zoster in immunocompetent patients	11-9-2010
170.	Lornoxicam 4mg + Eperisone 50mg tablet	For the improvement of myotonic conditions caused by neck shoulder arm syndrome, scapulohumeral periarthritis and low back pain in adult patients only	13-9-2010
171.	Pirfenidone film coated tablet ...200mg	For the treatment of idiopathic pulmonary fibrosis.	14-9-2010
172.	Beclomethasone Dipropionate IP 0.025% w/w + Neomycin Sulphate IP 0.5% w/w cream	Additional lower strength	15-9-2010
173.	Amlodipine 5mg/2.5mg + Valsartan 320mg/80mg + HCTZ 12.5mg/12.5mg tablet	Additional strength	21-9-2010
174.	Paracetamol 500mg/500mg + Thiocolchicoside 4mg/8mg tablet	For the treatment of acute inflammation conditions associated with spasm in adults only	21-9-2010
175.	Ketorolac Tromethamine 0.4% w/v + Moxifloxacin 0.5% w/v Ophthalmic solution	Additional lower strength	21-9-2010
176.	Nilotinib Capsules 150 mg.	Treatment of newly diagnosed adult patients with Philadelphia chromosome positive chronic Myeloid Leukemia (Ph+CML) in chronic phase	29-9-2010
177.	Levocloperastine (as Fendizoate) Suspension eq. to Levocloperastine HCl 20mg/ 5ml	For the treatment of non-productive cough in adult patients	29-9-2010
178.	Zileuton uncoated bilayered extended release tablet ...600mg	For the prophylaxis and chronic treatment of asthma in adults	30-9-2010
179.	Etodolac 400mg + Paracetamol IP 500mg tablet	Additional higher strength	1-10-2010
180.	Dried Aluminium Hydroxide Gel IP 600mg + Magnesium Hydroxide IP 300mg + Simethicone IP 25mg + Oxetacaine BP 10mg per 5ml syrup	For the treatment of symptoms of functional gastrointestinal disorders like irritable bowel syndrome, functional dyspepsia, peptic ulcer, gastroesophageal reflux disease which include smooth muscle spasms, flatulence, abdominal distension, hyperacidity, gastric distress, bloating etc.	5-10-2010
181.	S(-) Metoprolol Succinate ER eq. to S (-) Metoprolol Tartarate 25mg/50mg + Clopidogrel (IR) 75mg/75mg tablet	For the treatment of essential hypertension who need antiplatelet therapy especially for prophylaxis of atherothrombotic event	7-10-2010
182.	Exenatide Injection (Additional Indication)	Exenatide is a glucagon like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 Diabetes mellitus	9-10-2010
183.	Bimatoprost Ophthalmic Solution 0.01% w/v (Additional Strength)	Same as approved	9-10-2010
184.	Drospirenone + Ethinylestradiol tablets Same as approved	For the treatment of moderate Acne vulgaris in adult females, who have no known contra-indications to oral contraceptive therapy, and have achieved menarche. It should be used for the treatment of acne only if the patient desires an oral contraceptive for birth control	9-10-2010
185.	Etodolac USP 400mg + Tolperisone HCl 150mg tablet	For the treatment of acute inflammation conditions associated with spasm in adults only	11-10-2010
186.	Citicoline 500mg + Piracetam 400mg per 5 ml syrup	Additional dosage form	11-10-2010
187.	Thiocolchicoside 0.25% + Methyl Salicylate IP 100mg + Menthol IP 50mg + Absolute alcohol IP 50mg per gm gel	For the topical treatment of painful muscles spasms of skeletal musculature	11-10-2010
188.	Amlodipine Besylate IP Eq. to Amlodipine 10mg/5mg/2.5mg + Telmisartan 80mg/40mg/20mg + HCTZ 25mg/12.5mg/12.5mg tablet	For the treatment of essential hypertension	12-10-2010
189.	Pregabalin 150mg/75mg + Methylcobalamin 750mcg + Alpha Lipoic Acid 100mg + Pyridoxine 3mg + Folic Acid 1.5mg capsule	For the treatment of painful diabetic neuropathy in adults only	12-10-2010

190.	Ferrous Bisglycinate 60mg + Zinc Sulphate monohydrate Eq. to Zinc 14mg + Copper as Copper Sulphate 1 mg + Selenium as Selenomethionine 70mcg + Vitamin B6 IP 10mg + Methylcobalamin 1500mcg + Folic Acid 5mg + Fish oil 10/40 (DHA 200mg) 500mg capsule.	For Vitamin and mineral deficiency	13-10-2010
191.	Combipack of 21 tablets of FDC of Ethinylestradiol IP 0.03 mg + Levonorgestrel IP 0.15 mg and 7 tablets of Ferrous Fumarate IP 75mg (Eq. to 24.375 mg of Ferrous iron)	As contraceptive pill for women	13-10-2010
192.	Amitriptyline Hydrochloride IP 4%w/w + Ketamine HCL eq. to Ketamine 2% w/w per gm cream.	For the treatment of patients suffering from neuralgia	13-10-2010
193.	Paracetamol IP 500mg + Phenylephrine HCL IP 5mg +Caffeine (anhydrous) IP 30mg + Diphenhydramine HCL IP 25mg tablet.	For the treatment of fever associated with cold, nasal congestion in adults	13-10-2010
194.	Levocetirizine Dihydrochloride 2.5mg +Montelukast 5mg dispersible tablet	Additional strength	13-10-2010
195.	Calcium Citrate Maleate eq. to elemental Calcium 250mg + Vitamin D3 IP 200 IU tablet	For the treatment of calcium and Vitamin D deficiency states	13-10-2010
196.	Levonorgesterel 100mcg + Ethniyl Estradiol IP 20mcg tablet	(Additional indication) For the treatment of moderate Acne Vulgaris in women more than 18 years of age who have no therapy contraindications to oral contraceptive therapy, desire contraception, and have achieved menarche	13-10-2010
197.	Eberconazole 1% w/w + Mometasone Furate USP 0.1% w/w cream	For the treatment of mild to moderate inflamed cutaneous mycoses	13-10-2010
198.	Lubiprostone Soft Gelatin Capsules8mcg /24mcg	1. For the treatment of chronic constipation in adults. 2. For the treatment of irritable bowel syndrome with constipation (IBS-C) in women > 18 years old	16-10-2010
199.	Pazopanib (as Hydrochloride) film coated Tablets...200mg/400mg	For the treatment of patients with advanced renal cell carcinoma	16-10-2010
200.	Eltrombopag (as Olamine) Tablets ...25mg/ 50mg	For the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts)	16-10-2010
201.	Tolperisone HCl 150mg + Paracetamol IP 500mg tablet	For the treatment of patients with acute painful musculoskeletal conditions	21-10-2010
202.	Zaltoprofen film coated tablet ...80mg JP	For anti-inflammatory and analgesic activity in rheumatoid arthritis, osteoarthritis, low back pain, periarthritis of shoulder, cervicobrachial syndrome, postoperative, post-trauma, and post-dental extraction	31-10-2010
203.	Hyoscine Butylbromide 20 mg tablet (Additional Strength)	Same as approved	4-11-2010
204.	Cerebroprotein Hydrolysate injection (Lyophilised)1050 mg/2100mg (approx) equivalent to nitrogen.....30mg/ 60mg respectively	For amelioration of cranial injury, cerebrovascular pathological sequelae and aprosexia in dementia	4-11-2010
205.	Clebopride (as Malate) (1) Tablets. 0.5 mg Ph. Eur. (2) Syrup 0.1 mg/ml Ph. Eur. (3) Injection 1 mg/2ml Ph. Eur.	For the treatment of various disorders associated with altered gastrointestinal motility like non-ulcer dyspepsia (NUD) and / or chronic gastritis, gastroesophageal reflux disease (GERD), nausea and vomiting of organic or functional origin	4-11-2010

206.	Tolperisone HCl Mouth Dissolving tablet 50/100 mg (Additional Dosage Form)	Same as Approved	4-11-2010
207.	Oxybutynin Gel 100 mg	For the treatment of overactive bladder with the symptoms of urge urinary incontinence, urgency and urinary frequency	4-11-2010
208.	Dapoxetine (as Hydrochloride) Tablets ...30mg/60mg	For the treatment of premature ejaculation (PE) in men 18 to 64 years of age	13-11-2010
209.	Opipramol dihydrochloride Tablet 50mg/100mg	For the treatment of Generalised Anxiety Disorder (GAD) and Somatic Disturbances	13-11-2010
210.	Ondansetron Rapid Film Oral Strip 4/8 mg	For chemotherapeutic induced nausea and vomiting	16-11-2010
211.	Acebrophylline SR Tablet 200 mg	For the treatment of adult patients with Chronic Obstructive Pulmonary Disease (COPD) and bronchial asthma	23-11-2010
212.	Ammonium Lactate Cream 12% w/w	Indicated for the treatment of Dry, scaly skin(xerosis) and ichthyosis vulgaris and for temporary relief of itching associated with these condition.	3-12-2010
213.	Rabeprazole Sodium Powder oral suspension (sachet of 20 mg) (Additional Dosage Form)	Same as approved	3-12-2010
214.	Temsirolimus Concentrate for Infusion for Injection 25mg/ml	For the treatment of advanced renal cell carcinoma	11-12-2010
215.	Acetyl Cysteine Eye Drops 5% w/v	Indicated the relief of Dry eye symptoms associated with deficient tear secretion, impaired or abnormal mucus production	14-12-2010
216.	Clindamycin Palmitate HCl for Oral Solution 75mg/5ml	Indicated for the Prophylaxis against alpha-hemolytic(viridans group) streptococci before dental, oral and upper respiratory tract surgery	14-12-2010
217.	Deferasirox Tablet for Oral Suspension (Additional Dosage Form)	Same as approved	14-12-2010
218.	Ramelteon film coated tablets 8 mg	For the treatment of insomnia characterized by difficulty with sleep onset	15-12-2010
219.	Memantine ER Tablet 7mg/14 mg/21mg (Additional Strength)	Same as approved	17-12-2010
220.	Solution for haemofiltration and haemodialysis (Each unit contains two compartments A & B. Before reconstitution: • 1000 ml of electrolyte solution in Compartment A contains: Calcium Chloride 2H ₂ O 5.145gm Magnesium Chloride 2H ₂ O.... 2.033gm Lactic Acid...5.4gm • 1000ml of buffer solution in Compartment B contains: Sodium Chloride .. 6.45gm Sodium Bicarbonate .. 3.090gm)	For treatment of acute kidney disease (renal failure), as substitution solution in continuous haemofiltration and haemodiafiltration and as a dialysis solution in continuous haemodialysis	23-12-2010
221.	Pyridoxine HCl IP 3mg + Nicotinamide IP 100mg + Cyanocobalamin IP 15mcg + Folic Acid IP 500mcg + Chromium Picolinate USP 250mcg Tablet	For Mineral & Vitamins deficiency states in adult patients	23-12-2010
222.	Rosuvastatin Calcium IP 5mg/10mg + Fenofibrate BP 160mg/160mg tablet	Additional strength	29-12-2010
223.	Chlorhexidine Gluconate IP 1%w/v + Ethyl Alcohol IP 61%w/v solution	Surgical hand scrub & healthcare personnel hand wash	29-12-2010

List of Drugs approved during January to December 2011

Sl. 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	3-1-2011
2.	Ropinirole ER Tablet 1 mg. (Additional Strength)	Same as approved	4-1-2011
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	4-1-2011
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	5-1-2011
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	5-1-2011
6.	S (+) Etodolac 300mg+Thiocolchicoside 8mg Tablet	For the treatment of patients with acute painful musculoskeletal conditions	5-1-2011
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	5-1-2011
8.	Amlodipine Besilate IP Eq. to Amlodipine 5mg + Indapamide USP SR 1.5mg Tablet	For the treatment of mild to moderate hypertension	5-1-2011
9.	Metformin HCl IP 500mg + Alpha Lipoic Acid USP 200mg Tablet	For the treatment of patients with diabetic polyneuropathy	5-1-2011
10.	Spirolactone IP 25mg + Furosemide IP 40mg Tablet	Additional strength	5-1-2011
11.	Bicalutamide Tablet 150 mg.(Additional Strength and Indication)	Indicated either alone or as adjuvant to radical Prostatetomy or radiotherapy in Patients with Locally advanced Prostate cancer at High risk for disease Progression	5-1-2011
12.	Paracetamol Chewable Tablet 500 mg. (Additional Dosage Form)	Same as approved	5-1-2011
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	11-1-2011
14.	Dextromethorphan Extended Release Oral Suspension 30 mg per 5 ml	For the Relief of Persistent Dry irritating cough in adult patients Only	17-1-2011
15.	Hydroquinone USP 2% w/w + Tretinoin USP 0.025% w/w + Allantoin USP 1%w/w Gel	For treatment of hyper pigmentary disorders	31-1-2011
16.	Paracetamol Fast Release Tablet 500mg (Additional Dosage Form)	Same as approved	10-2-2011
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	For bowel cleansing prior to colonoscopy in adult patients only	11-2-2011

	0.74gm		
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	11-2-2011
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	11-2-2011
20.	Ursodeoxycholic Acid Suspension 125mg/5ml and 250 mg /5ml.	For the treatment of patients with chronic cholestatic liver disease	11-2-2011
21.	Iloperidone Tablets 1mg/2mg/ 4mg/6mg/8mg/10mg/12mg	For the acute treatment of adults with schizophrenia	17-2-2011
22.	Calf lung surfactant Intratracheal Suspension containing Phospholipids ..35mg (containing 26 mg phosphatidylcholine of which 16mg is disaturated phosphatidylcholine) Proteins .065mg (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	17-2-2011
23.	Baclofen ER Capsule 10 mg/50 mg (Additional Strength)	Same as approved	17-2-2011
24.	Dexketoprofen Trometamol ER Tablet 50 mg (Additional Strength)	Same as approved	21-2-2011
25.	Gatifloxacin Eye drop 5 mg/ml	For the treatment of bacterial conjunctivitis caused by susceptible strains	21-2-2011
26.	Paclitaxel Injection 30mg/100 mg/300 mg (Additional Indication)	Advanced squamous cell carcinoma of Head and Neck SCCHN: 1. Diagnosed but unresectable locally advanced SCCHN 2. Recurrent SCCHN, if surgery or radiation is not feasible 3. Palliative treatment of metastatic SCCHN	24-2-2011
27.	Eslicarbazepine Acetate Tablets 200mg/400mg/600mg/800mg	As an adjunctive therapy in adults with partial-onset seizures with or without secondary generalisation	7-3-2011
28.	Ketoprofen Plaster (Size - 7cm x 10 cm)	For the Relief of Musculoskeletal pain and Inflammation	9-3-2011
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	15-3-2011
30.	Dasatinib 20mg/50mg/70mg (Additional Indication)	Treatment of newly Diagnosed Adults with Chronic Myeloid Leukaemia (CML) in Chronic Phase	16-3-2011
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	21-3-2011
32.	Tioconazole Vaginal Gel 65mg per gm	For the local treatment of vulvo vaginal candidiasis in adult patients	22-3-2011
33.	Aspirin (EC Tablets) 75mg/ 75mg/150mg + Rosuvastatin (Granules) 5mg/10mg/10mg Capsules	For the treatment of dyslipidemia associated with atherosclerotic arterial disease with risk of Myocardial infarction, stroke or peripheral vascular disease	30-3-2011
34.	Ilaprazole Tablets 5mg/10mg	For the treatment of duodenal ulcer in adults only	5-4-2011
35.	Asenapine Maleate Sublingual Tablets 5mg/10mg	For acute treatment of schizophrenia in adults only	7-4-2011
36.	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	16-4-2011
37.	Tapentadol Hydrochloride Tablets 50mg/75mg/100mg	For relief of moderate to severe acute pain in adults 18 years of age or older	18-4-2011

38.	Cefixime Trihydrate IP Eq. to Anhydrous Cefixime 100mg/200mg + Ofloxacin IP 100mg/200mg Dispersible Tablet (Additional dosage form)	Same as approved	20-4-2011
39.	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	28-4-2011
40.	Dexketoprofen 50mg + Dicyclomine 20mg per 2ml Injection	For the treatment of acute colicky pain in adult patients	28-4-2011
41.	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	19-5-2011
42.	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	19-5-2011
43.	Brinzolamide Ophthalmic Suspension 1%w/v	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma	26-5-2011
44.	Besifloxacin Ophthalmic Suspension 0.6% w/v	For the treatment of bacterial conjunctivitis	31-5-2011
45.	Diclofenac (as EC Tablets) 25mg + Paracetamol 325 mg Capsule (Additional Strength)	Same as approved	31-5-2011
46.	Amlodipine 10mg/10mg+ Telmisartan 40mg/80mg Tablets (Additional Strength)	Same as approved	31-5-2011
47.	1. PROBIO: Each sachet (1g) contains: Total Probiotic.... Not less than 1.25 Billion CFU (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, Saccharomyces boulardii) 2. PROBIO & PREBIO (F)s Each sachet (1g) contains: Probio (CMP 5) Total Probiotic...Not less than 1.25 Billion CFU (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, Saccharomyces boulardii) Fructo Oligo Saccharides 100mg 3. PROBIO & PREBIO (D) Each sachet (1.3g) contains: Probio (CMP 5) Total probiotic... not less than 1.25 billion CFU (Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, Saccharomyces boulardii) Fructo Oligo Saccharides...1000mg	For the treatment of rotavirus diarrhoea	9-6-2011
48.	Paracetamol 325mg + Tramadol Hydrochloride 37.5 mg Tablets	Additional indication. (For Symptomatic Treatment of Moderate To Severe Pain.)	21-6-2011
49.	Silodosin Capsules 2 mg/4mg/8mg	For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adults only.	23-6-2011
50.	Tiapride Hydrochloride Tablets 25mg/50mg/100mg	For the treatment of agitation and aggressiveness in adult patients with cognitive impairment.	23-6-2011
51.	Fexofenadine 120mg + Montelukast 10mg Chewable tablet	Additional dosage form	7-7-2011

52.	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	27-7-2011
53.	Cefixime (SR) 400mg + Moxifloxacin (SR) 400 mg Tablets	For the treatment of lower respiratory tract infections in adults only	8-8-2011
54.	Alpha Lipoic acid 100mg + Folic acid 1.5mg + Methylcobalamin 1500mcg + Pyridoxine Hydrochloride 3mg + Vitamin D3 1000 IU Tablets	For the treatment of Diabetic neuropathy	10-8-2011
55.	Levosulpride (SR) 75 mg + Rabeprazole sodium IP (EC Pellets) 20mg Capsule	For the treatment of Gastro-oesophageal Reflux Disease (GERD)	19-8-2011
56.	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.	23-8-2011
57.	Diclofenac sodium (SR) 100mg + Eperisone Hydrochloride (SR) 150mg Capsules	For the treatment of patient with acute musculoskeletal spasm associated with low back pain.	24-8-2011
58.	Rosuvastatin Calcium eq. to Rosuvastatin 20mg/20mg + Fenofibrate BP 67.5mg/145mg Tablets	Additional Strength	24-8-2011
59.	Eletriptan Hydrobromide Tablets 20mg/40mg	For the treatments of Migraine with or without aura in adults	25-8-2011
60.	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	30-8-2011
61.	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)	30-8-2011
62.	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	13-9-2011
63.	Glutathione for Injection 600mg	For the treatment of alcoholic liver diseases like alcoholic fatty liver, alcoholic liver fibrosis, alcoholic liver cirrhosis, and hepatitis	14-9-2011
64.	Udenafil Tablet 100mg/200mg	For the treatment of erectile dysfunction	15-9-2011
65.	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	19-9-2011
66.	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	21-9-2011
67.	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	22-9-2011

68.	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 with a history of recent stroke or established peripheral arterial disease	22-9-2011
69.	Acrivastine Capsules 8mg	For the symptomatic relief of allergic rhinitis.	26-9-2011
70.	Tacalcitol ointment 4mcg	For the treatment of psoriasis vulgaris in adults only.	26-9-2011
71.	Each Combipack contains: (A) One tablet of Risedronate Sodium - Each film coated tablet contains: Risedronate Sodium (as Risedronate Sodium Hemipentahydrate) - 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	30-9-2011
72.	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.	12-10-2011
73.	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	19-10-2011
74.	Arterolane Maleate 150mg + Piperaquine Phosphate 750mg Tablet	Treatment of acute uncomplicated malaria infection due to Plasmodium falciparum in adults.	19-10-2011
75.	Tafluprost Eye Drops 0.0015% w/v	For the reduction of elevated intraocular pressure in open angle glaucoma and ocular hypertension.	21-10-2011
76.	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	24-10-2011
77.	Diazinon Flea Drops Spot on Dogs 30.0% w/w	For dogs infected with fleas.	11-11-2011
78.	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.	15-11-2011
79.	Epalrestat 50mg + Methylcobalamin 500mcg Tablets	For the treatment of Diabetic Neuropathy	16-11-2011
80.	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.	16-11-2011
81.	Ketorolac Tromethamine IP 4.00mg + Olopatadine Hcl eq. to Olopatadine 1.00mg + Benzalkonium Chloride IP 0.05mg Ophthalmic solution	For the treatment of seasonal allergic conjunctivitis in adults only	21-11-2011

82.	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	21-11-2011
83.	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	21-11-2011
84.	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	23-11-2011
85.	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.	28-11-2011
86.	Rosuvastatin Calcium IP eq to Rosuvastatin 5mg + Ezetimibe 10mg. (Additional Strength)	For the treatment of patients with primary hypercholesterolemia.	5-12-2011
87.	Tolperisone Hcl IP 150mg + Diclofenac IP 50mg Tablets	For the treatment of Patients with acute muscle/musculoskeletal spasm in adult	7-12-2011
88.	Paracetamol IP 325mg + Pamabrom USP 25mg Tablets	For the treatment of patient with pre-menstrual syndrome in adults only	7-12-2011
89.	Dosulepine Hcl 50mg/75mg + Methylcobalamin 1500mcg/1500mcg Tablets	For the treatment of neuropathic pain.	8-12-2011
90.	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.	8-12-2011
91.	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.	12-12-2011
92.	Montelukast Sodium IP eq.to Montelukast 10mg +Olopatadine Hcl 5mg Tablets	For the treatment of relief of symptoms of allergic rhinitis	16-12-2011
93.	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.	16-12-2011
94.	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.	16-12-2011
95.	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.	16-12-2011
96.	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	20-12-2011
97.	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 Elemental Zinc 5.5mg Syrup	For the treatment of Iron Deficiency Anaemia	22-12-2011

List of Drugs approved during January to December 2012

Sl. No	Name of Drug	Indication	Date of issue
1.	Ornidazole IP 1 % w/w + Povidone Iodine IP (0.5% w/w available Iodine) 5% w/w Ointment	For the prevention and treatment of surgical wound infections in adult patients undergoing surgery	3-1-2012
2.	Aceclofenac IP (Sustained released pellets) 200mg/ 200mg + Thiocolchicoside IP (Sustained released pellets) 8mg/16mg Capsules. (New Dosage Form)	For the treatment of acute inflammation conditions associated with spasm in adults only	4-1-2012
3.	Budesonide IP 1mg/0.5mg + Formoterol Fumarate Dihydrate IP eq to Formoterol Fumarate 20mcg/20mcg Respirator suspension. (Additional Indication)	In the regular treatment of patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD) with frequent symptoms and a history of exacerbations	4-1-2012
4.	Diclofenac Sodium IP (Enteric coated granules) 50mg + Eperisone Hcl IP (Tablet) 50mg Hard Gelatin Capsules. (New Dosage Form)	For the treatment of Patients with acute musculoskeletal spasm associated with low back pain	6-1-2012
5.	Degarelix for Injection 80mg/ 120mg per vial	For the treatment of adult patients with advanced hormone dependent prostate cancer	19-1-2012
6.	Linagliptin film coated Tablet 5mg	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Important limitations of use: 1. Should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis 2. Has not been studied in combination with insulin	23-1-2012
7.	Eribulin mesylate solution for injection 0.88mg / 2ml vial	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least two chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane unless patients were not suitable for these treatments	27-1-2012
8.	Plerixafor Injection 20mg/ml	In combination with Granulocyte Colony Stimulating Factor (G-CSF) to enhance mobilisation of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous hematopoietic stem cells transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma whose cells mobilise poorly	31-1-2012
9.	Cephalexin IP (as monohydrate) 200mg + Kanamycin IP (as monosulphate) 100,000 IU Suspension per 10 gm Intramammary Suspension	For the treatment of clinical mastitis in lactating dairy cows for bacteria susceptible to the combination of cephalexin and kanamycin such as Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus uberis and Escheria coli	7-3-2012
10.	Mucotrol Concentrated Oral Gel Wafer	For the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including oral mucositis/stomatitis (may be caused by chemotherapy or radiotherapy). Irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures of diseases and for diffuse aphthous ulcers	7-3-2012
11.	Ulinastatin for Injection 50000 IU/100000 IU	For the treatment of severe sepsis	3-4-2012
12.	Sterile Solution for Peritoneal Dialysis Each 1000 ml contains: Calcium chloride dihydrate 0.184 g/l + Glycine 0.51 g/l + L- Alanine 0.951 g/l + L- Arginine 1.071 g/l + L- Isoleucine 0.85 g/l + L- Histidine 0.714 g/l + L- Leucine 1.02 g/l + L- Lysine (as Hcl) 0.955 g/l + L-Methionine 0.85 g/l + L- Phenylalanine 0.57 g/l + L-Proline 0.595 g/l + L- Serine 0.51 g/l + L- Threonine 0.646 g/l + L-Tryptophan 0.27 g/l + L-Tyrosine 0.3 g/l + L-Valine 1.393 g/l + Magnesium chloride hexahydrate	As Nutritional supplements for malnourished renal failure patients (Albumin concentration lower than 35 g/litre) being maintained on peritoneal dialysis	18-4-2012

	0.051 g/l + Sodium chloride 5.38 g/l + Sodium lactate 4.48 g/l		
13.	Blonanserine Tablet 2mg/4mg/ 8mg	For the treatment of Schizophrenia in adult patients when first line treatment is ineffective	24-4-2012
14.	Etravirine Tablet 100mg	In combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretroviral agents. It should be used only in situations where other treatments have failed or cannot be used because of side effects	26-4-2012
15.	Ticagrelor Tablet 90mg	For the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non ST elevation Myocardial infarction (STEMI) including patients managed medically, and those who are managed with percutaneous those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG)	3-5-2012
16.	Clenbuterol Hydrochloride Solution for injection 30mcg/ml	For the treatment of equine respiratory diseases in horses where airway obstruction due to bronchospasm and/or accumulation of mucus is contributing factor and improved muco-ciliary clearance is desirable. The product should be used alone or as an adjuvant therapy. The product is of particular value in cases of: - Acute, sub-acute and chronic infections where the presence of mucus and/or micro-organisms may stimulate bronchospasm e.g. Bronchitis, broncholitis and Bronchopneumonia — Acute, sub-acute and chronic respiratory allergies. — Chronic obstructive pulmonary disease (COPD)	1-7-2012
17.	Apixaban Tablets 2.5mg	Prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective hip or knee replacement surgery	3-8-2012
18.	Ethyl esters of iodized fatty acids of poppy seed oil solution for injection 48%.	In Diagnostic Radiology: Lymphography and Diagnosis of liver lesions. (Diagnosis of the spread of malignant lesions, whether hepatic or not, by selective hepatic arterial injection). In Interventional Radiology: Embolization with surgical glues. (In association with surgical glues during vascular embolizations). In Endocrinology: Prevention of iodine deficiency disorders. (This treatment should only be used when other methods of supplementation, particularly iodization of salt and/or drinking water, cannot be undertaken)	22-8-2012
19.	Conivaptan Hydrochloride Injection 20mg/4ml	For the treatment of euvoletic hyponatremia (e.g. the syndrome of inappropriate secretion of antidiuretic hormone, or in the setting of hypothyroidism, adrenal insufficiency, pulmonary disorders, etc.) in hospitalized patients	21-8-2012

20.	Colesevelam Hydrochloride Tablets 625mg & Sachets for oral suspension 3.75gm/1.875 gm	Indicated as an adjunct to diet and exercise to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia as monotherapy or in combination with an hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin). Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	29-8-2012
21.	Tolvaptan Tablets 15/30mg	For the treatment of clinically significant hypervolemic and euvoletic hyponatremia [serum sodium < 125mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction], including patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH)	6-9-2012
22.	Agomelatine Tablets 25mg	For the treatment of major depression in adult patients aged 18 – 65 years only with normal liver functions	10-9-2012
23.	Almotriptan Tablet 6.25mg/ 12.5mg	For acute treatment of migraine attacks with a history of migraine with or without aura in adults	5-10-2012
24.	Choline Fenofibrate DR Capsule 45mg/135mg & DR Tablet 45mg/135mg.	For treatment of mixed lipidemia in combination with statins, severe hypertriglyceridemia	1-11-2012
25.	Trimethoxysilyl Quaternary Ammonium Chloride solution for spray inanimate surfaces for disinfection 0.71%	Surface protectant and disinfectant for persistent disinfection of all inanimate surfaces. Effective up to 14 days	16-11-2012
26.	Imipenem IP (Sterile) eq to anhydrous Imipenem 1 g + Cilastatin Sodium IP (sterile) eq to Cilastatin 1 g Powder for Injection (Additional strength)	For the treatment of serious lower respiratory tract infections, urinary tract infections, intra-abdominal, bone and joint infection, endocarditis and bacterial septicemia	28-6-2012
27.	Diclofenac Diethylamine BP 4.64 % w/v Eq. to Diclofenac Sodium IP 4.00 % + Absolute Alcohol IP 10.00 % v/v Topical Solution	For the Treatment of Acute Lower Back Pain	21-12-2012

List of Drugs approved during January to December 2013

Sl. 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	1-1-2013
2.	Telmisartan 20mg + Amlodipine Besylate Eq. to Amlodipine 2.5mg + Hydrochlorothiazide 6.25mg Tablets (Additional Strength)	For the Treatment of Essential Hypertension	3-1-2013
3.	Amlodipine besilate IP Eq. to Amlodipine 10mg + Indapamide SR 1.5 mg Tablet (Additional Strength)	For the treatment of mild to moderate Hypertension	2-1-2013
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.	18-1-2013
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.	28-1-2013
6.	Dabigatran Etexilate Mesilate eq to Dabigatran Etexilate 75mg/110mg/150mg	For the prevention of venous thromboembolic events in patients who have undergone orthopaedic surgery	11-2-2013

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.	20-2-2013
8.	Cefixime Tablets 200mg & Cefixime Oral Suspension 100mg/5ml	For the treatment of enteric (typhoid) fever.	22-2-2013
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	25-2-2013
10.	Saroglitazar 2mg/4mg Tablets	For the treatment of diabetic dyslipidemia and hypertriglyceridemia with type-2 diabetes mellitus not controlled by statin therapy	25-2-2013
11.	Tadalafil Tablet 2.5mg/5mg	1. For the treatment of erectile dysfunction. 2. For the treatment of erectile dysfunction with benign prostatic hyperplasia.	27-2-2013
12.	Azithromycin Tablet 250mg/500mg	For the treatment in uncomplicated multi drug resistant enteric fever only	6-3-2013
13.	Betahistine Dihydrochloride SR Tablets 24mg/32mg/48mg	For the symptomatic treatment of peripheral vertigo	14-3-2013
14.	Palonosetron Melt in Mouth Tablets 0.5mg	For prevention of chemotherapy induced nausea and vomiting	19-3-2013
15.	Iobitridol Solution for Injection Each 100mg solution contain 65.81g Iobitridol corresponding mass of Iodine 30gm	By intracavity route for Arthrography and Hysterosalpingography.	19-3-2013
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.	21-3-2013
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	8-4-2013
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.	8-4-2013
19.	Tolperisone HCl 450mg + Diclofenac Sodium IP 100mg SR tablets (Additional Strength)	For the treatment of Patients with acute muscle/musculo skeletal spasm in adult	12-4-2013
20.	Telmisartan IP 80mg + Hydrochlorothiazide IP 25mg uncoated bilayered tablet (Additional Strength)	For the treatment of hypertension as second line therapy	14-5-2013
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.	27-5-2013
22.	Garenoxacin Mesylate tablets 200mg	For the treatment of bacterial respiratory tract infection	7-6-2013
23.	Trimethoxysilyl Quaternary Ammonium Chloride 0.40% hand protectant and sanitizer	Hand Protectant and Sanitizer for external use. Effective up to 24 hours.	11-6-2013
24.	Sildenafil Citrate Orally Disintegrating Strips. 25mg/50mg (Additional Dosage Form)	For the treatment of erectile dysfunction.	5-7-2013
25.	Dextromethorphan Hydrobromide Extended Release suspension 30mg/5ml (Additional Dosage Form)	For the relief of persistent dry irritating cough in adults patients only.	1-8-2013.

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.	20-8-2013
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.	12-9-2013
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 Rutaceae 1000mg (MPFF) (Additional strength)	Acute hemorrhoid piles.	28-11-2013
30.	Artesunate injection. Each combi pack 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.	13-11-2013
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.	12-11-2013
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.	23-12-2013
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.	20-12-2013
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”.	19-12-2013
35.	Risperidone prolonged release suspension for injection (Deep Intramuscular Deltoid route using appropriate safety needle) (Additional route of administration)	Same as already approved	19-12-2013

List of Drugs approved during January to December 2014

Sl. No	Drug	Indication	Date
1.	Tolterodine Tartrate Extended release tablets 2mg/4mg (Additional Dosage Form)	For the treatment of overactive bladder with symptoms of urge urinary incontinence, urinary incontinence, urgency and frequency.	31-1-2014
2.	Bortezomib for injection 3.5mg (Sub-cutaneous route of administration as an alternate to intravenous route) (Additional route of administration)	Same as already approved	28-1-2014
3.	Paclitaxel Injection Concentrate for Nanodispersion 100mg and 300mg (Additional Dosage Form)	For the treatment of Breast cancer after failure of combination therapy metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.	22-1-2014
4.	Heparin Sodium Topical Solution 1000 IU/ml (Additional Dosage Form)	For the management of post infusion superficial thrombophlebitis.	16-1-2014
5.	Simethicone Orally disintegrating strip 62.5mg	For the treatment of flatulence and as adjuvant in hyperacidity.	14-11-2010
6.	Eltrombopag Olamine tablet 25/50mg (Additional Indication)	Indicated in patients with chronic hepatitis C Virus (HCV) infection for the treatment of thrombocytopenia to: Enable the initiation of interferon based therapy, optimise interferon based therapy.	7-4-2014
7.	Decitabine lyophilised powder for injection 50mg/20ml vial (additional indication)	For the treatment of adult patients aged 65 years and above with newly diagnosed de novo or secondary acute myeloid leukemia (AML), according to World Health Organisation (WHO) classification, who are not candidates for standard induction chemotherapy.	9-4-2014
8.	Glycopyrronium bromide inhalation powder hard capsule with inhaler. Each capsule contains 63mcg Glycopyrronium bromide eq. to Glycopyrronium 50 mcg.	Indicated as a once daily maintenance bronchodilator treatment to relieve symptoms of patients with Chronic Obstructive Pulmonary Disease (COPD).	1-4-2014
9.	Micafungin sodium for injection 100mg/vial (Additional Strength)	Treatment of patient with candidemia, acute Disseminated Candidiasis, Candida Peritonitis and abscesses. Treatment of patients with Esophageal Candidiasis, Prophylaxis of Candida and Aspergillus Infections in patients undergoing Hemopoietic stem cell transplantation. Treatment of patient with Fungemia, Respiratory mycosis, Gastrointestinal mycosis caused by Aspergillus sp..	2-5-2014
10.	Apixaban tablets 2.5mg/5mg (Additional Strength & Additional Indication)	Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF), including those with one or more risk factors, such as prior stroke or transient ischemic attack (TIA); Age \geq 75 years; hypertension; diabetes mellitus; symptomatic heart failure (NYHA Class \geq II). Compared to warfarin apixaban also results in less bleeding, including intracranial hemorrhage.	16-5-2014
11.	Mometasone furoate nasal spray 50 mcg/actuation (Additional Indication)	For the treatment of nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and pediatric patients 2 years of age and older.	21-5-2014
12.	Micronised Purified Flavonoid 1000mg (MPFF). "Each film coated tablet contains diosmin 900mg and flavonoids expressed as Hesperidine 100 mg of Micronised Purified Flavonoid fraction of Rutaceae 1000mg (MPFF)"	Acute hemorrhoid piles	28-11-13

13.	Gemcitabine HCl injection ready to use infusion bags Gemcitabine HCL equivalent to Gemcitabine 10mg per mL(100,120,130,140,150,160,170,180,190 and 200mL) (Approved as infusion bags)	Ovarian cancer-Gemcitabine injection in combination with carboplatin is indicated for the treatment of patients with advanced ovarian cancer that has replaced at least 6 months after completion of platinum based therapy. Breast Cancer-Gemcitabine injection in combination with Paclitaxel is indicated for the first line treatment of patients with meta static breast cancer after failure of prior anthracycline containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated. Non-small cell lung cancer-Gemcitabine injection is indicated in combination with cisplatin for the first line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or meta static (stage IV) non-	17-6-2014
14.	Tadalafil Orally Disintegrating Strip 10mg & 20mg (Additional dosage form)	For erectile dysfunction	30-7-2014
15.	Hydroxychloroquine Sulphate USP 400 mg tablets (Additional Indication)	As an adjunct to diet and exercise to improve glycemic control of patients on metformine, sulfonylurea combination in patients with Type II Diabetes.	28-7-2014
16.	Nevirapine Extended release tablet 400mg (Additional Strength)	For use in combination with other anti-retroviral agents for the treatment of HIV-1 infection in adults	1-7-2014
17.	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)”	Promoted for use in severe malaria including cerebral malaria as a second line in chloroquine resistant malaria cases only.	13-11-2013
18.	Cerebrolysin solution for injection. Each ml contains: Porcine brain derived peptide preparation (Cerebrolysine concentrate) 215.2mg	For amelioration of cranial injury, cerebrovascular pathological sequelae and aprosexia in dementia.	25-7-2014
19.	Artesunate powder for injection 60mg/vial along with 6ml ampoule of phosphate buffer solution (pH 8.0;0.30M)	For the treatment of severe Falciparum malaria in areas where there is evidence if quinine resistance	2-7-2014
20.	Montelukast sodium chewable tablet 4mg/5mg and Montelukast sodium film coated tablet 10mg.	As add on therapy in mild to moderate asthma in adequately controlled by inhaled cortico steroids and short active B2 agonist, Exercise induced broncho constriction.	26-2-2002
21.	Lactobacillus brevis CD2 Lozenges 100mg (corresponding to not less than 1 billion) of live, lyophilised, lactic acid bacteria, Lactobacillus brevis CD2. (Additional indication)	Prevention of radiotherapy and chemotherapy induced oral mucositis in cancer patients.	9-8-2014
22.	Rivaroxaban tablet 15/20mg (Additional strength/indication)	1. Treatment of deep vein thrombosis and for prevention of recurrent DVT and pulmonary embolism. 2. For the prevention of stroke and systemic embolism in patient with non-valvular arterial fibrillation.	2-9-14
23.	Hydroxychloroquine Sulphate Tablet 300mg (Additional strength/indication)	Indicated for the treatment of patients with lower body weight i.e 45 to 60kg in Rheumatoid arthritis, Systemic Lupus Erythematosus & Polymorphic Light Eruption	9-8-2014
24.	Ginkgo biloba extract Tablet 120mg (Additional strength)	For the treatment of dementia, vertigo and tinnitus in adult patients.	9-12-2014
25.	Bendamustine Hydrochloride lyophilised injection 25mg (Additional strength)	Treatment of patients with chronic lymphocytic leukemia	19-9-2014
26.	Metformin ER tablet 750mg (Additional strength)	As an adjunct to diet and exercise to improve glycemic control in adult patients with Type II Diabetes.	25-9-14

27.	Sorafenib tosylate tablet 200mg (Additional indication)	For the treatment of patients with locally advanced or meta static differentiated thyroid carcinoma refractory to radioactive iodine.	25-9-14
28.	Deferasirox Dispersible tablet 100/400mg (Additional indication)	Treatment of chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes aged 10 years and older.	26-9-2014
29.	IMATINIB mesilate 100/400mg tablets and 100 mg capsules (Additional indication)	Treatment of Paediatric patients with newly diagnosed Philadelphia chromosome positive acute Lymphoblastic Leukaemia (Ph+ALL) integrated with chemotherapy	9-9-2014
30.	Tapentadol Extended release tablet 100/150/200mg (Additional strength)	For use in in-patients under hospital setting for severe acute pain for a period not exceeding 5 days	9-12-13
31.	Olanzapine pamoate Prolonged release powder for suspension for IM injection (combipack) Each combipack contains a. Vial of Olanzapine pamoate Prolonged release powder for suspension. Each vial contains: Olanzapine pamoate monohydrate eq to Olanzapine..... 210mg/300mg/405mg. After reconstitution each ml of suspension contains 150mg. b. Vial of vehicle: 3ml clear, colourless to slight yellow solution contains: Manitol IP. ... 5.070%w/v Sodium carboxymethyl cellulose IP.... 0.770% w/v Polysorbate 80 IP.... 0.025%w/v HCL IP....q.s. NAOH IP....q.s Water for injection ...q.s. to 100%	For the treatment of schizophrenia	14-10-14
32.	Rivastigmine transdermal patch. Each Transdermal patch of 15cm ² contains Rivastigmine 27mg (Additional indication)	For the treatment of patients with severe dementia of the Alzheimer's type	28-10-2014
33.	Dabigatran Etxilate Mesilate hard gelatin capsule 75/110/150mg (Additional Indication)	1. Treatment of acute deep vein thrombosis (DVT) and /or pulmonary embolism (PE) and prevention of related death. 2. Prevention of recurrent deep vein thrombosis (DVT) and /or pulmonary embolism (PE) and related death	17-11-14
34.	Pegaspergase 3,750 IU/5 mL	Indicated as a component of multi agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia who are hypersensitive to asparaginase	7-3-2014
35.	Tulobuterol Transdermal Patch 0.5 mg/ 1.0 mg/2.0 mg	For treatment of patients with Asthma and COPD without co-morbidity	24-4-14
36.	Azacitidine 100 mg/ vial	For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome	29-4-14
37.	Azacitidine	For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome	23-7-14
38.	Regorafenib film coated tablet 40 mg	For the “treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine, oxaliplatin and irinotecan-base chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy”.	1-7-14
39.	Roflumilast Tab 500 mcg	For the treatment of severe chronic obstructive pulmonary disease (COPD) (FEV1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.	17-7-14
40.	Dimethyl Fumarate delayed release 120 mg/240 mg Tablet	For “Relapsing remitting multiple sclerosis”	27-8-14

41.	Alogliptin Tablet 6.25 mg/12.5 mg/ 25 mg	“To improve glycemic control in combination with other glucose lowering medicinal products including insulin when these together with diet and exercise, do not provide adequate glycemic control or as monotherapy as adjunct to diet and exercise to improve glycemic control in adults aged 18 years or older with type 2 Diabetic mellitus.”	27-8-14
42.	Axitinib Tablet 1mg/5mg	For the “treatment of advanced renal cell carcinoma after failure of one prior systemic therapy”	18-9-14
43.	Ulinastatin Injection	For the treatment of mild to severe acute pancreatitis.	19-9-14
44.	Canagliflozin Tablet 100/300mg	“Indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type-2 Diabetic Mellitus”.	17-11-14
45.	Levosulpiride 75/150/200 mg (add. Strength)	75 mg tablet: For the treatment of gastro intestinal problem like functional dyspepsia, nausea, vomiting and diabetic gastroparesis. 150/200mg: For the treatment of depression and schizophrenia in adults.	9-12-14
46.	Nitrofurantoin dispersible tablets 50 mg (add. Strength/ dosage form)	for the treatment of acute uncomplicated urinary tract infections (acute cystitis) caused by susceptible strains of E coli or staphylococcus saprophyticus	15-12-14
47.	Methylcobalamin orally disintegrating strips 1500mcg (add. Dosage form/ indication)	for the treatment of peripheral neuropathy and diabetic neuropathy	17-12-14
48.	Paclitaxel suspension for injection Conc. For nanodispersion 100/300mg (add. Indication)	management of endometriosis associated pain	18-12-14
49.	Lapatinib tablet 250mg (Additional indication)	lapatinib in combination with trastuzumab , indicated for the treatment of patients with hormone receptor — negative metastatic breast cancer whose tumours over express HER2/neu (ErbB2) and who have progressed on prior trastuzumab therapy in combination with chemotherapy in the metastatic setting.	22-12-14
50.	Medroxyprogesterone acetate suspension for injection s.c . Single dose container with 104mg Medroxyprogesterone acetate in 0.65 ml suspension for injection (SAYNA<< PRESS) (Additional route/ strength/indication)	Indicated for the management of endometriosis-associated pain.	18-12-14
51.	Empty Hydroxy Propyl Methyl Cellulose Capsules	NA	11-1-2011

List of Drugs approved during January to December 2015

Sl. No	Name Of Drug	Indication	Date of Approval
1	Levocetirizine ODS 2.5mg /5mg (Additional dosage form)	For allergic rhinitis and chronic urticaria.	14-1-2015
2	Decitabine Injection 30mg/vial (Additional pack size)	<p>1. For treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French- American-British subtypes(refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and intermediate-1, intermediate-2, and high-risk international Prognostic Scoring System groups.</p> <p>2. For the treatment of adult patients aged 65 yrs and above with newly diagnosed de novo or secondary acute myeloid leukemia, according to WHO classification, who are not candidates for standard induction chemotherapy.</p>	13-2-2015

3	Meloxicam ODT 7.5mg/15mg (Additional dosage form)	Non-steroidal anti-inflammatory.	23-2-15
4	Ruxolitinib Tablet 5mg/15mg/20mg (Additional indication)	Treatment of patients with polycythemia vera who are resistant to or intolerant of hydroxyurea.	23-2-2015
5	Gadopentetic acid dimeglumine salt injection 469mg/1ml (0.5mmol) (Additional indication)	For use in MRI in adult patients to facilitate visualization of lesions with abnormal vascularity in the body (excluding heart).	23-2-2015
6	Pazopanib Tablet 200mg/400mg (additional indication)	For the treatment of patients with advanced Soft Tissue Sarcoma (STS) who have received prior chemotherapy.	23-2-2015
7	Eribulin mesylate solution for injection 0.88mg in 2ml vial (Add. Indication)	For the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimens for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or meta static setting unless patients were not suitable for these treatments.	18-2-2015
8	Abiraterone acetate Tablet 250 mg (Additional Indication)	For the treatment of meta static castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated, with prednisone or prednisolone.	27-3-2015
9	Indomethacin Injection 1mg/vial (additional Dosage form)	To close a hemodynamically significant patent ductus arteriosus (PDA) in premature infants weighing between 500g and 1750g when after 48 hrs. usual medical management (e.g. fluid restriction, diuretics, digitalis, respiratory support, etc.) is ineffective. Clear-cut clinical evidence of hemodynamically significant patent ductus arteriosus should be present, such as respiratory distress, a continuous murmur, a hyperactive precordium, cardiomegaly and pulmonary plethora on chest X-ray.	30-4-2015
10	Ketorolac ODS 10mg (Additional Dosage form)	For the treatment of short-term management of post-operative pain and musco-skeletal pain.	29-4-2015
11	Tiamulin hydrogen fumarate solution for injection 162 mg/ml (additional Dosage form)	For treatment and prevention of swine dysentery caused by Branchyspira hydodysenteriae. The product is not appropriate for use for the prevention of disease at the level of herd treatment but should only be used for prevention of swine dysentery in individual animals with a known history of exposure to diseased animals.	17-4-2015
12	Montelukast Orally Disintegrating Strips 4mg/5mg/10mg (additional Dosage form)	For the Relief of perennial allergic rhinitis in adults & pediatric patients 6 months of age and older.	29-5-2015
13	Apixaban Tablets 2.5/5mg (additional Indication)	Treatment of deep vein thrombosis (DVT) and pulmonary Embolism (PE), and prevention of Recurrent DVT and PE in adult patients.	29-5-2015
14	Ruxolitinib 10mg tablet (additional Strength)	1. For the treatment of patients with myelofibrosis including primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis 2. Treatment of patients with polycythemia vera who are resistant to or intolerant of hydroxyurea.	29-5-2015
15	Lorazepam Orodispersible Tablet 1mg/2mg (additional Dosage form)	For the management of anxiety disorders or for the short term relief of symptoms of anxiety or anxiety associated with depressive symptoms.	29-5-2015

16	Brimonidine topical gel 0.33% (Add. Dosage form/indication)	For the topical treatment of persistent (non-transient) facial erythema of rosacea in adults 18 years of age or older.	18-6-2015
17	Rivaroxaban tablet 2.5mg (add. strength)	Rivaroxaban 2.5mg tablet, co-administered with Acetylsalicylic acid (ASA) alone or with ASA plus Clopidogrel or Ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.	13-7-2015
18	Lamotrigine ER Tablet 25mg/50mg/100mg/200mg	Add-on therapy for partial and secondary generalised tonic-clonic seizures.	6-8-2012
19	Feracrylum 3% solution	For the management of post-operative wounds cuts, Abrasions as a Haemostatic Agent cum anti-septic.	13-2-2002
20	Feracrylum 3% gel	For the management of post-operative wounds cuts, Abrasions as an Haemostatic Agent cum anti-septic.	13-2-2002
21	Arteether injection 150mg/mL	Indicated for the treatment of severe malaria including cerebral malaria and as a second line in chloroquine resistant malaria cases only.	3-12-2010
22	Everolimus dispersible Tablet 0.1mg/0.25mg (additional Indication)	For the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Everolimus should be used in combination with tacrolimus and corticosteroids.	21-8-2015 (Condition: Phase-IV trial duly approved by CDSCO shall be conducted in statistically significant number of patients.)
23	Everolimus Tablet 0.25mg/0.5 mg/0.75mg/1.0mg (additional Indication)	For the prophylaxis of organ rejection in patients receiving a hepatic transplant. In liver transplantation, Everolimus should be used in combination with tacrolimus and corticosteroids.	21-8-2015 (Condition: Phase-IV trial duly approved by CDSCO shall be conducted in statistically significant number of patients.)
24	Cetrorelix Acetate injection 0.25mg/0.5ml in 0.5 ml pre-filled syringe. (Additional pack size)	Prevention of premature ovulation in patients undergoing a controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques.	26-8-2015
25	Exenatide 2 mg powder and solvent for prolonged release suspension for injection in a pre-filled pen (s.c. Injection) (Additional strength)	For treatment of type 2 diabetes mellitus in combination with Metformin Sulphonylurea Thiazolidinedione Metformin and Sulphonylurea Metformin and Thiazolidinedione In Adults who have not achieved adequate glycemic control on maximally tolerated doses of these oral therapies.	9-9-2015
26	Vitamin D3 (Cholecalciferol) Orally disintegrating strips 2000 IU (additional Dosage form)	For the treatment of Vitamin D3 deficiency.	1-10-2015
27	Dexamethasone Intravitreal implant 0.7mg (Additional Indication)	For the treatment of visual impairment due to Diabetic Macular Edema (DME) who are pseudophakic or who are	12-10-2015

		considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.	
28	Zolpidem Tartarate Orally disintegrating Tablet 5mg/10mg (Additional dosage form)	For insomnia.	12-10-2015
29	Etodolac i.m injection 400mg/2ml (Additional dosage form)	For the treatment of post operative orthopaedic pain.	14-12-2015

List of Drugs approved during January to December 2016

Sl. No.	Name of Drug	Indication	Date of issue
1	Nintedanib soft Gelatin Capsule 100/150mg	For the treatment of Idiopathic Pulmonary Fibrosis (IPF).	11-3-2016
2	Cisatracurium Besylate Bulk & 2mg/ml injection	As an adjunct to general anaesthesia, to facilitate tracheal intubation and to Provide skeletal muscle relaxation during surgery.	14-3-2016
3.	Fomepizole Bulk & 1.5gm/ Ampoule	As an antidote for Ethylene glycol or Methanol used poisoning or for use in suspected Ethylene glycol or Methanol ingestion, either alone or in combination with hemodialysis.	14-3-2016
4	Tofacitinib Tablets 5 mg(Tofacitinib Citrate)	“For the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to Methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs)”.	1-4-2016
5	Nintedanib Soft Gelatin Capsule 100/150mg (Nintedanib ethanesulfonate)	“In combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumor histology after line chemotherapy”.	1-4-2016
6	Ceftaroline Fosamil Injection 600 mg/Vial	“For the treatment of adult (≥ 18 years of age patients with community-acquired pneumonia”.	9-5-2016
7	Panobinostat Hard Gelatin Capsules 10mg/15mg/20mg (Panobinostat lactate)	“In combination with bortezomib and dexamethasone, is indicated for the treatment of patients with multiple myeloma, who have received at least 1 prior therapy”	27-5-2016
8	Bepotastine Besilate Bulk & Bepotastine Besilate 1.5 %w/v Ophthalmic solution	“For the treatment of itching associated with allergic conjunctivitis”	8-6-2016
9	Ibutilide Bulk & Ibutilide Fumarate Injection 0.1mg/ml	“For the rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm. Patient with atrial arrhythmias of longer duration are less likely to respond to Ibutilide Fumarate Injection. The effectiveness of Ibutilide has not been determined in patients with arrhythmias of more than 90 days in duration”.	10-6-2016
10	Acotiamide Hydrochloride Bulk & Tablet 100mg	“For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia”.	6-7-2016
11	Sacubutril+ Valsartan film coated tablets 50mg/100 mg/200mg	“To reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction”.	14-7-2016
12	Lurasidone Hydrochloride Bulk & Lurasidone Hydrochloride Tablets 40mg/80mg	“For the treatment of Patients with Schizophrenia”	18.07.16
13	Fenticonazole Nitrate Vaginal Capsule 600 mg	“For the treatment of vulvovaginal candidiasis”	10-8-2016

14	Palbociclib Capsules 75mg/100mg/125 mg	“Palbociclib is a kinase inhibitor indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease”.	11-8-2016
15	Midodrine Hydrochloride 2.5 mg Tablet	“For the treatment of symptomatic orthostatic hypotension”	2-9-2016
16	Phospholipids Fraction from Bovine Lung (surfactant) 50 mg/vial	“Preventive use in premature neonates with a high risk of respiratory Distress Syndrome”	12-9-2016
17	Dolutegravir 50 mg Tablet & Bulk (Dolutegravir Sodium)	“Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults weighing more than 40 kg”	7-11-2016
18	Alcaftadine Eye Drops 0.25% w/v & Bulk	“For the prevention of itching associated with allergic conjunctivitis in patients between the age group 10 to 60 years”	21-11-2016
19	Bepotastine Besilate Bulk		23-11-2016
20	Lenvatinib 4mg/10mg Hard Gelatin Capsules (Lenvatinib Mesylate)	“For the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer”	2-12-2016
21	Perampanel 2mg/4mg/6mg/8mg/10mg/12mg Tablets	“The adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older”	2-12-2016
22	Azilsartan Medoxomil Bulk & 40mg/80mg Tablets	“Indicated for the treatment of hypertension in adults patients, either alone or in combination with other antihypertensive agents”	9-12-2016

List of Drugs approved during January to December 2017

Sl. No.	Name of Drug	Indication	Date of issue
1	Hydrocortisone Aceponate 0.584mg/ml Cutaneous Spray Solution (Vet.)	For symptomatic treatment of inflammatory and pruritic dermatosis in dogs.	6-1-2017
2	Dexlansoprazole Delayed Release Capsule 30/60mg & Bulk	For the treatment of (i) Healing of all grades of erosive esophagitis (EE). (ii) Maintaining healing of EE and relief of heartburn. (iii) Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).	16-1-2017
3	Carfilzomib Sterile Lyophilized Powder for Injection 60mg/vial (50ml vial)	Relapsed or refractory multiple myeloma Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.	17-1-2017
4	Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.	18-1-2017

5	Trametinib 0.5mg/2mg Tablets (Trametinib Dimethyl Sulfoxide)	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.	18-1-2017
6	Alectinib 150mg Capsules (Alectinib Hydrochloride)	For the treatment of patients with anaplastic lymphoma kinase (ALK)-Positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.	23-1-2017
7	Eliglustat 84mg Capsules (Eliglustat Tartrate or Hemitartrate Salt)	For the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an appropriate test.	31-1-2017
8	Pasireotide long-acting release 20/40/60mg powder for suspension for injection (Additional Indication) (Pasireotide pamoate)	For the treatment of patients with acromegaly who have had an inadequate response to surgery and/ or for whom surgery is not an option.	14-2-2017
9	Etonogestrel 68 mg implant	For use by women to prevent pregnancy.	15-2-2017
10	Bepotastine Besilate 1.5 %w/v Ophthalmic solution	For the treatment of itching associated with allergic conjunctivitis	22-2-2017
11	Dienogest 2mg Tablets	For the management of Pelvic pain associated with Endometriosis	9-3-2017
12	Eprinomectin 0.5% for beef and dairy cattle (vet.)	It is indicated for the treatment and control of gastrointestinal roundworm (including inhibited Ostertagia ostertagi), lungworm, grubs, sucking and biting lice, chloriopic and sarcoptic-mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle.	14-3-2017
13	Bepotastine Besilate 10 mg Tablets	For the treatment of allergic rhinitis	27-3-2017
14	Prucalopride 1mg/2mg Tablet & Bulk (Prucalopride Succinate)	For the treatment of chronic idiopathic constipation in adults in whom laxatives fail to provide adequate relief	13-4-2017
15	Teriflunomide 14 mg tablets	For the treatment of patients with relapsing form of multiple sclerosis	13-4-2017
16	Pomalidomide 1mg/2mg/3mg/4mg Capsules & Bulk	In combination with dexamethasone, for patient with patient multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.	1-5-2017
17	Sofosbuvir 400 mg +Velpatasvir 100 mg Tablet	For the treatment of adult patients with - chronic Hepatitis C virus, Genotype 1, 2, 3, 4, 5 or 6 infection. - Without cirrhosis or with compensated cirrhosis - With decompensated with chronic for use in combination with Ribavirin.	4-5-2017
18	Velpatasvir Bulk		4-5-2017
19	Osimertinib 40 mg/80 mg Film coated Tablets (Osimertinib Mesylate)	For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy	29-5-2017

20	Argatroban Hydrate Bulk & Injection 250 mg/2.5 ml	(1) For prophylaxis or treatment of thrombosis in adult patients with Heparin induced thrombocytopenia (HIT). (2) As an anticoagulant in adults patients with or at risk for heparin-induced thrombocytopenia undergoing percutaneous coronary intervention (PCI)	30-5-2017
21	Fluralaner chewable tablets 112.5 mg/250 mg/500mg/1000mg/1400 mg	For the treatment of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile Ixodes ricinus, Ixodes hexagonus, Ixodes scapularis, Ixodes holocyclus, Dermacentor reticulatus, Dermacentor variabilis and Rhipicephalus sanguineus) and flea (Ctenocephalides felis and Ctenocephalides canis) killing activity for 12 weeks. Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. the onset of effect is within 8 hours of attachment for fleas (C. felis) and 12 hours of attachment for ticks (I. ricinus) The product effectively controls environmental flea population in area to which treated dogs have access. The product can be used as part of an treatment strategy for the control of Flea Allergy Dermatitis (FAD)	30-5-2017
22	Fluticasone Furoate (100 mg mcg) and Vilanterol Trifenatate (25 mcg) powder for inhalation	Indicated for the maintenance treatment of the airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/ or emphysema and to reduce exacerbation of COPD in patients with an exacerbation history.	29-6-2017
23	Mirabegron Prolonged Release Tablet 25 mg/50 mg	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	12-7-2017
24	Delamanid 50 mg tablet	For the use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability	2-8-2017
25	Mirabegron Prolonged Release Tablet 25 mg /50 mg & Bulk	Symptomatic treatment of urgency, increased micturition frequency and / or urgency incontinence as may occur in patients with over active bladder (OAB) Syndrome	18-8-2017
26	Efonidipine Hydrochloride Ethanolate Bulk & Tablets 10 mg/20mg/40mg	Indicated for the management of • Hypertension • Renal parenchymal hypertension • Angina	28-8-2017
27	Brivaracetam Film Coated Tablets 50mg/75mg/100mg	As adjunctive therapy in the treatment of partial -onset seizures in patients 16 years of age and older with epilepsy	7-9-2017
28	Treosulfan Bulk & injection 5g/vial	For the conditioning treatment prior to haematopoietic stem-cell transplantation	26-9-2017
29	Ribociclib 200 mg Film coated Tablets	In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of post menopausal women with the hormone receptor (HR)-Positive, human epidermal growth factor receptor 2 (HER2)-Negative advanced or metastatic breast cancer	27-9-2017

30	Dienogest Bulk & 2mg Tablet	For the management of Pelvic pain associated with Endometriosis	28-9-2017
31	Apremilast bulk & film coated tablets 10 mg/20 mg/30 mg	for treatment of patients with moderate to severe plaque psoriasis who are candidate for phototherapy or systemic therapy	13-10-2017
32	Arbekacin bulk & Injection 200mg/4ml	Treatment of following infections caused by Methicillin resistant Staphylococcus aureus (MRSA)", sepsis pneumonia	20-10-2017
33	Benestermycin Intra-mammary suspension (vet.)	For the treatment of subclinical mastitis at drying off, and the prevention of new bacterial infections of the udder during the dry period in dairy cows, caused by bacteria susceptible to penicillin and framycetin	3-11-2017
34	Midostaurin 25 mg Capsules	<ul style="list-style-type: none"> • In combination with standard induction and consolidation chemotherapy followed by single agent in maintenance of therapy for adult patients with newly diagnosed with acute myeloid leukemia (AML) who are FLT-3 Mutation positive. • For the treatment of adult patients with advanced systemic mastocytosis (Advanced SM) 	9-11-2017
35	Tenofovir Alafenamide Fumarate bulk & 25 mg Tablets	For the treatment of chronic Hepatitis B virus infection in adults with compensated liver disease	10-11-2017
36	Arteolane Maleate and Piperaquine phosphate Dispersible tablets (37.5 mg +187.5 mg	Indicated in children aged 6 months to 12 years for the treatment of: <ul style="list-style-type: none"> - Acute uncomplicated Plasmodium falciparum malaria infection - Acute uncomplicated Plasmodium Vivax malaria infection 	24-11-2017
37	Macitentan Bulk and Tablets 10 mg	Macitentan is an endothelin receptor antagonist (ERA)l indicated for the treatment of Pulmonary arterial hypertension (PAH, WHO group I) to delay disease progression	7-12-2017

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Sl. No.	Drug Name	Composition	Indication	Date of Approval
1	Pegaspargase injection 3750 IU per vial	Each vial contains: Pegaspargase 3750 IU per vial	As a component of multi agent chemotherapeutic regiment for the treatment of patients with acute lymphoblastic leukaemia who are hypersensitive to L-Asparaginase.	04-01-2018
2	Cefditoren Pivoxil dry powder for suspension 100mg/5ml (Additional Indication)	Each 5ml reconstituted suspension contains: Cefditoren Pivoxil equivalent to Cefditoren 100mg	For the treatment of mild to moderate infection also in children's of (2 months to 12 years of age) which are caused by susceptible strains of the designated microorganisms in the condition listed below: <ul style="list-style-type: none"> • Acute Bacterial Exacerbation of Chronic Bronchitis • Community-Acquired pneumonia • Pharyngitis/Tonsillitis • Uncomplicated Skin and skin - structure infection 	04-01-2018
3	Eltrombopagolamine tablets 12.5mg (additional strength & indication)	Each film coated tablet contains: Eltrombopag olamine equivalent to Eltrombopag olamine as free acid 12.5mg	1. Chronic ITP : for Adults For the treatment of thrombocytopenia in patients with chronic immune (idiopathic) Thrombocytopenic purpura (ITP) who have had an insufficient response to	06-02-2018

			<p>corticosteroids, immunoglobulins, or splenectomy. (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).</p> <p>For Paediatric patients aged 1 year and above:</p> <p>Thrombocytopenia in paediatric patients 1 year and older with immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).</p> <p>2. For the treatment of patients with chronic Hepatitis C virus (HCV) infection for the treatment of thrombocytopenia to: Enable the initiation of interferon based therapy, optimize interferon based therapy.</p> <p>With the condition: to be sold by retail on the prescription of Haematologist only</p>	
4	Alectinib Capsules 150mg (additional indication)	Each hard gelatin capsule contains: Alectinib 150mg equivalent to Alectinib hydrochloride 161.3mg	<p>First-line treatment of patients with Anaplastic Lymphoma Kinase (ALK) - positive locally advanced or metastatic non-small cell lung cancer (NSCLC).</p> <p>With the condition: to be sold by retail on the prescription of Oncologist only.</p>	05-03-2018
5	Fulvestrant 250mg/5ml injection (additional indication)	Each 5ml pre-filled syringe contains: Fulvestrant 250mg ethanol (96%)-10% w/v	<p>For the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy</p> <p>With the condition: to be sold by retail on the prescription of Oncologist only.</p>	20-03-2018
6	Bendamustine hydrochloride injection 90mg/ml (0.5ml vial & 2.0 ml vial) (additional indication)	Each ml contains: Bendamustine hydrochloride 90mg ethanol 4.33% w/v	<p>Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment.</p> <p>With the condition: to be sold by retail on the prescription of Oncologist/Specialist only.</p>	23-03-2018
7	Methotrexate injection prefilled syringe 15mg/0.3ml, 20mg/0.4ml and 25mg/0.5ml (Additional strength & indication)	<p>Each 0.3ml prefilled syringe ml contains: Methotrexate 15mg</p> <p>Each 0.4ml prefilled syringe ml contains: Methotrexate 20mg</p> <p>Each 0.5ml prefilled syringe ml contains: Methotrexate 25mg</p>	<p>It is indicated in treatment of</p> <ol style="list-style-type: none"> 1. Active rheumatoid arthritis in adult patients. 2. Polyarthritic forms of severe, active juvenile idiopathic arthritis, when the response to nonsteroidal anti-inflammatory drug (NSAIDs) has been inadequate, 3. Severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids and severe psoriatic arthritis in adult patients. 4. Mild to moderate Crohn's disease either alone or in combination with corticosteroids in adult patients refractory or intolerant to thiopurines. 	09-03-2018

8	Sildenafil power for oral suspension 10mg/ml (Additional dosage form)	Each ml of reconstituted suspension contains: Sildenafil citrate equivalent to 10mg, Sodium benzoate 4.375mg	Adults: Treatment of adult patients with pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity. Efficacy has been shown in primary pulmonary hypertension and pulmonary hypertension associated with connective tissue disease. Paediatric population: Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease. With the condition: to be sold by retail on the prescription of Cardiologist only.	20-03-2018
9	Dydrogesterone tablet 10mg (additional indication)	Each film coated tablet contains: Dydrogesterone 10mg	Luteal support as part of an Assisted Reproductive Technology (ART) treatment. With the condition: to be sold by retail on the prescription of Gynaecologist only.	06-04-2018
10	Febuxostat tablet 60mg & 20mg (Additional Strength)	Each film coated tablet contains: Febuxostat 60mg & 20mg	For the treatment of chronic hyperuricemia in conditions where urate deposition has already occurred (including a history, or presence of tophus and/or gouty arthritis)	06-04-2018
11	Posaconazole injection 300mg/16.7ml (18mg/ml) (additional strength & dosage form)	Each injection contains: Posaconazole 300mg/16.7ml	For prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. With the condition: to be sold by retail on the prescription of Specialist only.	13-04-2018
12	Teriflunomide tablet 7mg (Add. Lower strength)	Each film coated tablet contains: Teriflunomide 7mg	For the treatment of patients with relapsing form of multiple sclerosis. With the condition: to be sold by retail on the prescription of Neurologist only.	07.05.2018
13	Apremilast film coated tablet 10/20/30mg (Additional Indication)	Each film coated tablet contains: Apremilast-10mg, 20mg, 30mg	For the treatment of adult patients with Active psoriatic Arthritis.	11.05.2018
14	Aripiprazole tablet 2mg (additional strength)	Each uncoated tablet contains: Aripiprazole-2mg	For the treatment of Schizophrenia in adolescent patients (13 to 17 years of age) With the condition: to be sold by retail on the prescription of Psychiatrist only.	11.05.2018
15	Dextromethorphan HBr Lozenges 10mg (Add. dosage form & strength)	Each lozenges contains: Dextromethorphan HBr-33.33% Complex 30mg eq. to Dextromethorphan HBr 10mg	Cough suppressant for the relief of acute nonproductive (dry, tickly) cough associated with respiratory tract infection in adult patients only.	11.05.2018
16	Voglibose Orally Disintegrating Strips 0.2mg (Modified dosage form)	Each Orally Disintegrating Strips contains: Voglibose 0.2mg & 0.3mg	For improvement of postprandial hyperglycaemia in diabetes mellitus, when only diet and/or exercise or oral hypoglycaemic drugs or insulin preparation in addition to diet and/or exercise do not result in adequate glycemic control.	11.05.2018

17	Tranexamic acid tablet 1000mg (Additional strength)	Each film coated tablet contains: Tranexamic acid-1000mg.	For the treatment of menorrhagia	21.05.2018
18	Eltrombopag Olamine Tablet 75mg (Additional strength)	Each film coated tablet contains: Eltrombopag Olamine as free acid-75mg	<p>1. For the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.(It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts).</p> <p>2. Indicated in patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia to: a. Enable the initiation of interferon based therapy. b. Optimize interferon based therapy</p> <p>3. For the treatment of patients with severe aplastic anaemia (SAA) who have had an insufficient response to immunosuppressive therapy</p> <p>4. For the treatment of thrombocytopenia in paediatric patients 1 year and older with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy. (It should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. It should not be used in an attempt to normalize platelet counts). With the condition: to be sold by retail on the prescription of Hematologist only.</p>	29.05.2018
19	Thyroxine Sodium Tablet 37.5 mcg (Additional strength)	Each uncoated tablet contains: Thyroxine Sodium eq. to Anhydrous Thyroxine Sodium. 37.5 mcg.	<p>1. As replacement or supplemental therapy in patients of any age or state (including pregnancy) with hypothyroidism of any etiology except transient hypothyroidism during the recovery phase of sub-acute thyroiditis resulting from thyroid dysfunction, primary atrophy or partial or total absence of the thyroid gland or from the effects of surgery, radiation or drugs with or without the presence of goiter, including sub-clinical hypothyroidism; secondary (pituitary) hypothyroidism and tertiary (hypothalamic) hypothyroidism.</p> <p>2. As a pituitary TSH suppressant in the treatment or prevention of various types of euthyroid goites, including thyroid nodules, sub-acute or chronic lymphocytic thyroiditis (Hashimoto's) multi-nodular goiter and in conjunction with surgery and radioactive iodine therapy in the management of thyrotropin-dependent well differentiated papillary or follicular carcinoma of the thyroid.</p>	08.06.2018
20	Dabrafenib Hard Gelatin Capsule 50mg.& 75mg (Additional indication)	Each Hard Gelatin Capsule contains: Dabrafenib Mesylate eq. to Dabrafenib 50mg & 75mg	<p>Dabrafenib in combination with Trametinib for the treatment of adult patients with advanced non-small cell lung cancer with BRAF V600 mutation.</p> <p>With the condition: to be sold by retail on the prescription of Oncologist only.</p>	08.06.2018
21	Trametinib Tablet 0.5mg & 2mg (Additional indication)	Each Film coated tablet contains: Trametinib 0.5mg & 2mg	<p>Trametinib in combination with Dabrafenib for the treatment of adult patients with advance non-small cell lung cancer with a BRAF V 600 mutation.</p> <p>With the condition: to be sold by retail on the prescription of Oncologist only.</p>	08.06.2018

22	Azacitidine for injection 50mg/vial (Additional strength)	Each vial contains: Azacitidine, 50mg Lyophilized power for injection (for subcutaneous or Intravenous use)	For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome. With the condition: to be sold by retail on the prescription of Oncologist only.	22.06.2018
23	Nilotinib Capsules 50mg (Additional strength & add. indication)	Each Capsule contains: Nilotinib 50mg	1. Paediatric patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukaemia (CML) in the chronic phase. 2. Paediatric patients with chronic phase Philadelphia Chromosome Positive (CML) with resistance or intolerance to prior therapy including imatinib. With the condition: to be sold by retail on the prescription of Oncologist only.	22.06.2018
24	Fulvestrant 250mg/5ml injection (additional indication) (for IM use only)	Each 5ml pre-filled syringe contains: Fulvestrant USP 250mg Ethanol (96%) BP-10% w/v	In combination with Palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women who have received prior endocrine therapy". With the condition: to be sold by retail on the prescription of Oncologist only.	13.07.2018
25	Ganciclovir Sodium powder for Infusion 500mg (additional indication) (for IV use only)	Each vial contains: Ganciclovir 500mg (In the form of the sodium salt)	For the treatment of cytomegalovirus (CMV) disease in immunocompromised individuals and for the prevention of CMV disease in patients with drug-induced immunosuppression following organ transplantation or cancer chemotherapy. With the condition: to be sold by retail on the prescription of a Specialist only.	13.07.2018
26	Nepafenac Ophthalmic Suspension 0.3%w/v (Additional strength)	Each ml contains: Nepafenac 3.0mg	For the treatment of pain and inflammation associated with cataract surgery. With the condition: to be sold by retail on the prescription of Ophthalmologist only.	13.07.2018
27	Tadalafil Orally Disintegrating Strip 5mg (Additional strength)	Each Orally Disintegrating Strip contains: Tadalafil 5mg	For the treatment of Erectile Dysfunction	13.07.2018
28	Delamanid Tablets 50mg (additional indication)	Each film coated tablet contains: Delamanid 50mg	In exceptional cases and after a careful benefit/risk assessment Delamanid treatment can be initiated in children >6 years of age, for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability. With the condition: For the use in Revised National Tuberculosis Control Program (RNTCP).	27.07.2018
29	Osimertinib Film coated tablet 40mg and 80mg (Additional indication)	Each film coated tablet contains: Osimertinib 40mg, 80mg	As first-line treatment of patients with locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) whose tumors have Epidermal Growth Factor Receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitutions mutations. With the condition: To be sold by retail on the prescription of Oncologist only.	03.08.2018

30	Nicotine Polacrilex Orally disintegrating strips 2mg & 4mg (New dosage form)	Each Orally disintegrating strips contains: Nicotine Polacrilex eq. to Nicotine 2mg, 4mg	To reduce the withdrawal symptoms, including nicotine craving, associated with quitting the smoking and quitting chewed tobacco and gutkha containing tobacco	17.08.2018
31	Zolmitriptan Orally disintegrating strips 2.5mg & 5mg (Additional Dosage form)	Each Orally disintegrating strips contains: Zolmitriptan 2.5mg & 5mg	For Acute treatment of migraine with or without aura in adults.	10.08.2018
32	Ethyl esters of Iodidzed fatty acids of Poppy Seed Oil solution for injection (Lipodol Ultra Fluid 10ml) (Additional Indication)	Each ampoule (10ml) contains: Ethyl esters of Iodidzed fatty acids of Poppy Seed Oil Iodine content 48% i.e. 480mg iodine per ml	Conventional Trans-Arterial Chemo-Embolization (cTACE) of Hepatocellular Carcinoma (HCC) in adults.	06.09.2018
33	Methylcobala min nasal spray 250mcg/spray (New Dosage form)	Each 0.1ml contains: Methylcobalamin 500mcg Benzalkonium chloride (As preservative) 0.02% w/v	Treatment of Vitamin B12 deficiency in patients without having neurological involvement.	28.09.2018
34	Apomorphine Hydrochloride injection 10mg/ml (2ml and 5ml Ampoule) (subcutaneous use only) (Add. Dosage form and add. indication)	Each ml contains: Apomorphine hydrochloride 10mg	Treatment of disabling motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which persist despite individually titrated treatment with levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists. With the condition: to be sold by retail on the prescription of Neurologist only.	28.09.2018
35	Carfilzomib for Injection 30mg/vial (Lyophilized injection) (Additional Strength)	Each vial contains: Carfilzomib 30mg	<ul style="list-style-type: none"> Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy. With the condition: to be sold by retail on the prescription of Oncologist only.	28.09.2018
36	Nilotinib hard Capsules 150mg & 200mg (Additional indication)	Each Capsule contains: Nilotinib 150mg & 200mg	1. Treatment of Paediatric patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukaemia (CML) in the chronic phase. 2. Treatment of Paediatric patients with chronic phase Philadelphia Chromosome Positive (CML) with resistance or intolerance to prior therapy including imatinib. With the condition: to be sold by retail on the prescription of Oncologist only.	18.10.2018
37	Dasatinib film coated tablet 20mg, 50mg, 70mg and 100mg (Additional indication)	Each film coated tablet contains: Dasatinib 20mg, 50mg, 70mg and 100mg	Treatment of Paediatric patients with Philadelphia Chromosome Positive Chronic myeloid leukemia (Ph+ CML) in chronic phase. With the condition: to be sold by retail on the prescription of Oncologist only	18.10.2018

38	Nifedipine Extended Release Tablet 60mg (Add. Strength and indication)	Each Extended release film coated tablet contains: Nifedipine 60mg	<ul style="list-style-type: none"> • Vasospastic Angina, • Chronic stable Angina (Classical effort-Associated Angina), • Hypertension. <p>With the condition: to be sold by retail on the prescription of Cardiologist only.</p>	18.10.2018
39	Levetiracetam injection 500mg/100ml, 1000mg/100ml, and 1500mg/100ml. (Infusion bottle) (Additional dosage form)	Each 100 ml Infusion bottle contains: Levetiracetam in 0.82% sodium chloride (500mg/100ml) Levetiracetam in 0.75% sodium chloride (1000mg/100ml) Levetiracetam in 0.54% sodium chloride (1500mg/100ml)	<p>As adjunctive therapy in adult (16 years and older) with the following types of seizures when oral administration is temporarily not feasible.</p> <ul style="list-style-type: none"> • Partial onset seizures, • Myoclonic seizures in patients with juvenile myoclonic epilepsy, • Primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy <p>With the condition: to be sold by retail on the prescription of Neurologist only.</p>	27.10.2018
40	Nepafenac Ophthalmic Suspension 0.3%w/v (Additional Indication)	Each ml contains: Nepafenac 3.0mg	<p>For the treatment of post-operative pain and inflammation associated with cataract surgery.</p> <p>With the condition: to be sold by retail on the prescription of Ophthalmologist only.</p>	09.11.2018
41	Ibuprofen soft gelatine capsules 400mg. (New Dosage form)	Each soft gelatin capsule contains Ibuprofen 400mg	For chronic arthritic disorder and painful musculoskeletal conditions.	20.11.2018
42	Everolimus tablets 2.5 mg (Additional Indication)	Each tablets contains: Everolimus 2.5 mg	<p>Treatment of patients with Progressive neuroendocrine tumors of pancreatic origin (PNET) with unresectable, locally advanced or metastatic disease,</p> <p>Treatment of patients with Advanced Renal Cell Carcinoma (RCC).</p> <p>With the condition: To be sold by retail on the prescription of Oncologist only.</p>	05.12.2018
43	Clonazepam Mouth Dissolving tablets 0.25/0.5/1.0/2.0mg (New Dosage Form)	Each uncoated mouth dissolving tablet contains: Clonazepam 0.25/0.5/1.0/2.0 mg	<p>Treatment of seizure disorders (Petit mal and its variant, akinetic and myoclonic seizures), Panic disorder & add-on therapy in acute mania.</p> <p>With the condition: To be sold by retail on the prescription of Neurologists or Psychiatrist only.</p>	10.12.2018
44	Divalproex Sodium Oral Solution 250mg/5ml (Additional Strength)	Each 5 ml contains: Divalproex 250mg	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.	21.12.2018
45	Ivermectin Cream 1.0% w/w (New Dosage form)	Each Gram contains: Ivermectin 1.0% w/w	<p>Treatment of inflammatory lesions of rosacea.</p> <p>With the condition: To be sold by retail on the prescription of Dermatologist only.</p>	21.12.2018

List of drugs approved from SND Division from 01.01.2019 to 31.12.2019.

Sl. No.	Drug Name	Composition	Indication	Date of Approval
1	Donepezil Hydrochloride Orally Disintegrating Strips (Additional dosage form)	Each Orally Disintegrating Strips contains: Donepezil Hydrochloride 5/10 mg	For the treatment of mild to moderate severe Alzheimer's Dementia. With the condition: To be sold by retail on the prescription of Neurologists only.	11.01.2019
2	Tapentadol Hydrochloride capsule 50mg (New dosage form)	Each capsule contains: Tapentadol Hydrochloride 50mg	For relief of moderate to severe acute pain in adults 18 years of age or older.	30.01.2019
3	Midodrine Hydrochloride tablet 2.5mg, 5mg and 10mg (Additional strength)	Each tablet contains: Midodrine Hydrochloride 2.5mg, 5mg and 10mg	It is indicated in the treatment of symptomatic orthostatic hypotension. With the condition: To be sold by retail on the prescription of Cardiologists only.	20.02.2019
4	Ribociclib film coated tablet 200mg (Additional indication)	Ribociclib succinate 254.40mg eq. To Ribociclib 200mg	Ribociclib in combination with an aromatase inhibitor for the treatment of pre/peri-menopausal or post-menopausal women, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer, as initial endocrine-based therapy. With the condition: To be sold by retail on the prescription of an Oncologist only.	13.03.2019
5	Azacitidine for injection 150mg/vial (Additional strength)	Each vial contains: Azacitidine. 150mg Lyophilized powder for injection (for subcutaneous or Intravenous use)	For the treatment of adult patients with all subtypes of Myelodysplastic Syndrome. With the condition: to be sold by retail on the prescription of an Oncologist only.	25.03.2019
6	Lenvatinib capsule 4mg/10mg (Additional Indication)	Each capsule contains: Lenvatinib mesylate 4.90mg eq. To Lenvatinib 4mg, Lenvatinib mesylate 12.25 mg eq. To Lenvatinib 10mg.	For the first line treatment of patients with unresectable hepatocellular carcinoma. With the condition: to be sold by retail on the prescription of an Oncologist only.	26.03.2019
7	Primidone tablet 50mg (Additional Strength)	Each uncoated tablet contains: Primidone USP 50mg	It is indicated for the management of grand mal and psychomotor (temporal lobe) epilepsy. It is also of value in the management of focal or jacksonian seizures, myoclonic jerks and akinetic attacks. Management of essential tremor. With the condition: To be sold by retail on the prescription of an Neurologist only.	15.04.2019
8	Amisulpride orodispersible tablet 50/100/200/300/400mg (New dosage form)	Each uncoated Oro dispersible tablet contains: Amisulpride 50/100/200/300/400mg	For acute and chronic schizophrenic disorders, in which positive and negative symptoms are prominent, including patients characterised by predominant negative symptoms. With the condition: To be sold by retail on the prescription of a Psychiatrist only.	03.05.2019
9	Progesterone solution for Injection 25mg/1.119ml vial (Add. Dosage form and add. route of administration)	Each vial (1.119 ml) contains: Progesterone 25mg (22.35mg/ml) (For subcutaneous or intramuscular use only)	It is indicated in adults for luteal support as part of an Assisted Reproductive Technology (ART) treatment program in infertile women who are unable to use or tolerate vaginal preparations. With the condition: To be sold by retail on the prescription of Gynaecologists only.	17.05.2019

10	Azilsartan medoxomil tablet 20/40/80mg (Additional lower Strength)	Each uncoated tablet contains: Azilsartan Kamedoxomil equivalent to Azilsartan medoxomil 20/40/80mg	Indicated for the treatment of hypertension in adult patients either alone or in combination with other antihypertensive agents. With the condition: To be sold by retail on the prescription of a Cardiologist only.	27.05.2019
11	Everolimus Tablet 0.25mg/0.5mg/0.75mg/1.0mg (Additional indication)	Each film coated tablet contains: Everolimus 0.25mg/0.5mg/0.75mg/1.0mg	Prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving an allogeneic renal or cardiac transplant. In kidney and heart transplantation, Certican should be used in combination with ciclosporin for microemulsion and Corticosteroids. With the condition: To be sold by retail on the prescription of Cardiologist only.	27.05.2019
12	Diclofenac sodium 2% Topical Solution (New route of administration)	Each 1 gram of solution contains: Diclofenac sodium 20mg	For the treatment of pain of osteoarthritis of the knees.	03.06.2019
13	Artesunate for injection 120mg with phosphate buffer 0.3M (Additional strength)	Each combi pack contains: a) Artesunate for injection 120mg Each vial contains: Artesunate IP 120mg b) Phosphate Buffer 0.3M (12ml) Each ampoule contains: Anhydrous Disodium Hydrogen Phosphate BP 4.0% w/v Potassium dihydrogen phosphate BP 0.2% w/v	Indicated for the treatment of severe falciparum malaria in areas where there is evidence of quinine resistance	26.06.2019
14	Tranexamic acid injection IP 100mg/ml (Additional Indication)	Each ml contains: Tranexamic acid IP 100 mg/ml	Indicated for short term use in prophylaxis and treatment in patients at high risk of per-and post-operative hemorrhage following: a) Prostatectomy. b) Conisation of the cervix. c) Surgical procedures and extractions in hemophiliacs	26.07.2019
15	Rivaroxaban tablets 2.5mg (Add. Indication)	Rivaroxaban tablets 2.5mg	Rivaroxaban 2.5mg tablet, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events. With the condition: To be sold by retail on the prescription of Cardiologists only.	30.07.2019
16	Olaparib 100 mg and 150 mg tablet (Additional Indication)	Olaparib 100 mg and 150 mg tablet	for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy With the condition: To be sold by retail on the prescription of Oncologist only.	30.07.2019
17	Tapentadol Hydrochloride 25.000 milligram (mg) Capsules (Additional Lower Strength)	Tapentadol Hydrochloride 25.000 milligram (mg) Capsules	For relief of moderate to severe acute pain in adults 18 years of age or older	30.07.2019

18	Leuprolide 22.50mg depot Injection Powder for prolonged-release suspension for injection (Depot injection for I.M. use only) (Add. strength)	Each vial contains : Leuprolide acetate 22.5mg	Treatment of advanced Prostatic cancer. With the condition: To be sold by retail on the prescription of Oncologist only.	07.08.2019
19	Clobazam Tablets IP 2.5mg & 7.5mg (Add. lower strength).	Each tablet contains: Clobazam 2.5mg & 7.5mg	As an adjunctive therapy in patients with refractory epilepsy. With the condition: To be sold by retail on the prescription of Neurologist/Psychiatrist only.	07.08.2019
20	Sildenafil for oral suspension 10mg/ml (Add. Indication)	Each ml of reconstituted suspension contains: Sildenafil citrate IP equivalent to Sildenafil 10mg	For the treatment of pulmonary arterial hypertension (WHO Group I) in adults to improve exercise ability and delayed clinical worsening. With the condition: To be sold by retail on the prescription of Cardiologist only.	09.08.2019
21	Pantoprazole dual-release gastro-resistant tablet 80mg (New Dosage form)	Each dual-release gastro-resistant tablet contains: Pantoprazole sodium equivalent to Pantoprazole 80mg	For the treatment of moderate to severe refractory Gastro-oesophageal reflux disease (GERD) for 4 weeks only.	02.09.2019
22	Pirfenidone tablet 400 mg (Add. Strength)	Each film coated tablet contains : Pirfenidone 400mg	For the treatment of idiopathic pulmonary fibrosis. With the condition: To be sold by retail on the prescription of Pulmonologist only.	02.09.2019
23	Olopatadine HCl ophthalmic solution 0.7% w/v (Add. strength)	Each ml contains: Olopatadine HCl 0.7% w/v Benzalkonium chloride 0.015% w/v	For the treatment of ocular itching associated with allergic conjunctivitis. With the condition: To be sold by retail on the prescription of Ophthalmologist only.	06.09.2019
24	Ibrutinib hard gelatin capsule 140mg (Add. indication)	Each capsule contains: Ibrutinib 140mg	For the treatment of patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL). With the condition: To be sold by retail on the prescription of Oncologist only.	11.09.2019
25	Ibrutinib hard gelatin capsule 140mg (Add. indication)	Each capsule contains: Ibrutinib 140mg	For the treatment of patients with Waldenstrom's macroglobulinemia	11.09.2019
26	Desonide Ointment 0.05% (Add. Dosage form)	Desonide topical ointment 0.05%	for sub-acute to chronic steroid responsive dermatoses.	26.09.2019
27	Atorvastatin calcium tablet 30/60 mg (Add. Strength)	Each film coated tablet contains : Atorvastatin calcium equivalent to Atorvastatin 30/60 mg	1. As an Adjunct to Diet to Reduce Elevated Total Cholesterol and Triglyceride Levels in Patients with Primary Hypercholesterolemia and Mixed Dyslipidemia (Type IIa and IIb). 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 With the condition: To be sold by retail on the prescription of Cardiologist only.	27.09.2019

28	Desloratadine tablets 10mg (Additional strength)	Each film coated tablet contains : Desloratadine 10mg	For the treatment of Chronic Idiopathic Urticaria in patients who have not responded to the standard 5mg dose of Desloratadine.	27.09.2019
29	Diclofenac sodium Rectal Solution 25 % w/v with applicator (Add. dosage form)	Each ml contains: Diclofenac sodium 25%w/v Each Squirt (0.2ml) delivers: Diclofenac Sodium 50 mg	Mild to moderate pain in adults.	27.09.2019
30	Perampanel tablets 2mg /4mg/6mg/8mg/10mg/12mg (Additional indication)	Each film coated tablet contains : Perampanel 2mg /4mg/6mg/8mg/10mg/12mg	For the adjunctive treatment of primary generalized tonic-clonic seizures in patients with epilepsy aged 12 years and older. With the condition: To be sold by retail on the prescription of Neurologist only.	27.09.2019
31	Ribociclib Film Coated Tablet 200mg (Additional Indication)	Ribociclib Succinate 254.40 mg equivalent to Ribociclib 200 mg	Indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER-2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine based therapy or in women who have received prior endocrine therapy. Warning: To be sold by retail on the prescription of oncologist only.	04-10-2019
32	Cinidipine Tablet 20 mg (Additional Strength)	Each Film Coated Tablets contain Cinidipine 20mg	For the treatment of mild to moderate hypertension	11-10-2019
33	Glycopyrronium Solution Inhalation Solution 25mcg (For nebulisation) (Add. Dosage form)	Each 2ml contains Glycopyrrolate equivalent to Glycopyrronium 25mcg in isotonic solution	For the long term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema	14-11-2019
34	Cefpodoxim Proxetil Sustained Release Tablet 200/400mg (Add. Dosage form)	Each film coated sustained release Tablet contains: Cefpodoxime Proxetil, Equivalent to Cefpodoxime 200mg & 400mg	Acute bronchitis, exacerbations of chronic bronchitis, pneumonia, sinusitis, recurrent chronic tonsillitis, pharyngitis and acute otitis.	03.12.2019
35	Ivermectin Topical lotion 0.5% w/w	Each ml contains: Ivermectin 0.5% w/w	For the topical treatment of head lice infestation in patients 6months of age and older.	03.12.2019
36	Lenvatinib Capsules 4mg and 10mg (Additional Indication)	Each capsule contains Lenvatinib mesylate 4.90 mg equivalent to Lenvatinib 4mg and Lenvatinib mesylate 12.25mg equivalent to Lenvatinib 10 mg.	In combination with everolimus, for the treatment of patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. Warning: To be sold by prescription of a "Oncologist" only.	04.12.2019
37	Bilastine Oral Solution 2.500 mg/ml (Add. Dosage form)	Each ml contains: Bilastine 2.5000 mg	Symptomatic treatment of allergic rhino- conjunctivitis (seasonal and perennial) and urticaria. Bilastine is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.	10.12.2019
38	Pregabalin Extended Release Tablets 82.50 mg and 165mg	Each film coated Extended Release Tablet contains: Pregabalin 82.50 mg/165 mg	For treatment of peripheral neuropathic pain in adults.	12.12.2019
39	Clobetasol Propionate Topical Foam 0.5% w/w (Add.dosage form)	contains: Clobetasol Propionate 0.05% w/w Phenoxyethanol 1.0% w/w	Treatment of Inflammatory and pruritic manifestation of corticosteroid responsive dermatoses in patients 12 years of age or older.	16.12.2019

40	Clobetasol Propionate Cream, 0.025% w/w (Add.Strength)	Each gram of cream contains: Clobetasol Propionate 0.25mg	Indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.	16.12.2019
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List of drugs approved from SND Division from 01.01.2020 to 31.12.2020

Sl. No.	Drug Name	Composition	Indication	Date of Approval
1	Betahistine Dihydrochloride Orally Disintegrating Strips 16mg/24mg (New Dosage form)	Each Orally Disintegrating Strips contains: Betahistine Dihydrochloride 16mg/24mg	Indicated in the treatment of Menier's syndrome, Characterized by unilateral or bilateral tinnitus, vertigo, sensorineural hearing loss	02-01-2020
2	Posaconazole Gastro-Resistant Tablet 100 mg (Modified Release dosage form)	Each-Gastro-Resistant Tablet contains: Posaconazole 100 mg	For Prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. Posaconazole Gastro Resistant tablets are indicated in patients 13 years of age and older Warning: To be sold by retail on the prescription of Specialist only.	03-01-2020
3	Pirfenidone tablet 600 mg (Additional strength)	Each Film coated Tablet contains: Pirfenidone...600mg	For the Treatment of idiopathic pulmonary fibrosis Warning: To be sold by retail on the prescription of Pulmonologist only.	08-01-2020
4	Saroglitazar Tablet 2mg/4 mg (Additional indication)	Each uncoated tablet contains: Saroglitazar..... 2/4 mg	Type 2 Diabetes mellitus-as an add-on therapy to metformin	13-01-2020
5	Enzalutamide Soft Capsule 40 mg (Additional indication)	Each soft capsules contains Enzalutamide...40 mg	In the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated Warning: To be sold by retail on the prescription of Oncologist only.	23-01-2020
6	Canagliflozin 100 mg and 300 mg Tablet (Additional Indication)	Each film coated tablet contains: Canagliflozin 100mg/300mg	To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.	17-02-2020
7	Norethisterone Acetate Controlled Release Tablet 10 mg (Additional Dosage form & Indication)	Each film coated controlled release tablet contains: Norethisterone Acetate 10mg	To arrest bleeding in women with dysfunctional uterine bleeding due to hormonal imbalance.	24-02-2020
8	Lidocaine Hydrochloride 2% Solution (Additional Dosage Form)	Each ml contains: Lidocaine Hydrochloride 20mg	Indicated in adults: • For the production of topical anesthesia of irritated or inflamed mucous membranes of the mouth and pharynx. • For reducing gagging during the taking of X-ray pictures and dental impressions.	25-02-2020

9	Saroglitazar Tablets 4mg (Additional Indication)	Each uncoated tablet contains: Saroglitazar 4 mg	Noncirrhoic Non-Alcohol Steatohepatitis	02-03-2020
10	Itraconazole Capsule 200 mg (Additional Strength)	Each capsule contains: Itraconazole 200 mg	For the treatment of onychomycosis of the toenail due to Trichophyton rubrum or T. mentagrophytes in non-immunocompromised patients Warning: To be sold by retail on the prescription of a Specialist only.	03-03-2020
11	Nepafenac Ophthalmic suspension 0.3% w/v (Additional Indication)	Each ml contains: Nepafenac 3mg	Reeducation in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients Warning: To be sold by retail on the prescription of a Opthamologists only.	03-03-2020
12	Bisoprolol Fumarate tablet 1.25 mg (Additional strength)	Each film coated tablet contains: Biosoprolol Fumarate 1.25 mg	For the treatment of congestive heart failure (CHF)	04-03-2020
13	Pirfenidone Tablets 267 & 801 mg (Additional Strength)	Each film coated tablet contains: Pirfenidone 267mg/801 mg	For the treatment of idiopathic pulmonary fibrosis Warning: To be sold by retail on the prescription of a Pulmonologist only.	04-03-2020
14	Pegaspargase Injection 3750 IU/5ml (Additional Indication)	Each 5ml vial contains: Pegaspargase Injection 3750 IU	Injection as first-Line chemotherapeutic agent for treatment of patients with acute Lymphoblastic Leukemia (ALL) Warning: To be sold by retail on the prescription of a Oncologist only.	04-03-2020
15	Norethisterone Acetate Controlled Release Tablet 15 mg (Additional Strength)	Each film coated controlled release tablet contains: Norethisterone Acetate 15 mg	To arrest bleeding in women with Heavy Menstrual Bleeding (HMB)/abnormal Uterine Bleeding (AUB) due to hormonal imbalance Warning: To be sold by retail on the prescription of a Gynaecologist/Obstertrician only.	09-03-2020
16	Estriol Tablets 1mg/2mg (Additional strength)	Each uncoated Tablet contains: Estriol 1mg/2mg	Estrogen deficiency symptoms due to menopause Warning: To be sold by retail on the prescription of a Gynaecologist only.	09-03-2020
17	Busulfan Injection 60 mg/10ml (Additional Strength)	Each 10 ml vial contains: Buslfan 60mg	In combination with cyclophosphamide as a conditioning regimen prior to allogenic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia Warning: To be sold by retail on the prescription of a Oncologist only.	09-03-2020
18	Ulipristal Acetate Tablet 30 mg (Additional strength& indication)	Each film coated tablet contains: Ulipristal acetate 30 mg	Emergency contraception within 120 hrs (5 days) of unprotected sexual intercourse or contraceptive failure Warning: To be sold by retail on the prescription of a Gynaecologist only.	11-03-2020
19	Canagliflozin Tablet 100/300 mg (Additional Indication)	Each film coated tablet contains: Canagliflozin 100/300 mg	To reduce the risk of end-stage kidney disease (ESKD), doubling of serum creathinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria 300mg/day	11-03-2020
20	Nintedanib Soft Gelatin Capsules 100/150 mg (Additional Indication)	Each soft gelatin capsule contains: Nintedanib Ethanesulfonate equivalent to Nintedanib 100/150 mg	For the treatment of systemic sclerosis associated interstitial Lung Disease (SSc-ILD) Warning: To be sold by retail on the prescription of a Pulmonologist only.	20-03-2020

21	Oxaliplatin Injection 50 mg/vial & 100 mg/vial (Additional Dosage Form)	Each Vial contains: Sterile Solution of Oxaliplatin 50mg and 100mg	For the treatment of advanced colorectal cancer. Warning: To be sold by retail on the prescription of an oncologist only.	29-04-2020
22	Metformin Hydrochloride Prolonged Release Tablets 500mg (Additional Indication)	Each Prolonged Release Tablets contains: Metformin Hydrochloride 500mg	For the treatment of Polycystic Ovary Syndrome (PCOS) with established insulin resistance WARNING: To be sold by retail on the prescription of a RMP only In the package insert - Special warnings and precautions: Pregnancy: “There are no adequate and well-controlled studies in pregnant women with Metformin and Metformin should not be used during pregnancy unless clearly needed”	05-05-2020
23	Olaparib 100 mg and 150 mg Tablets (Additional Indication)	Each Film coated tablet contains: Oloaparib...100mg/150 mg.	Olaparib is indicated as monotherapy for the Maintenance treatment of adult patients with germline BRCA-mutated metastatic adenocarcinoma of the pancreas whose disease has not progressed on first-line platinum-based chemotherapy “WARNING: To be sold by retail on the prescription of Oncologist only”	06-05-2020
24	Bortezomib For injection 2.5mg/ml (Additional Pack Size)	Each Vial contains: Bortezomib 2.5 mg	• For the treatment of patients with multiple myeloma • For the treatment of patients with mantle cell lymphoma who have received at least one prior therapy. WARNING: To be sold by retail on the prescription of Oncologist only” which shall be in red box;	12-05-2020
25	Sodium Fluoride varnish (50mg/ml) (Dental Suspension) (New Dosage Form)	Each ml of Dental Suspension contains: Sodium Fluoride.....50 mg	• For the prevention of caries in children and adults as part of a comprehensive control programme, for the: - prevention of recurring (or marginal) caries - prevention of progression of caries - prevention of decalcification around orthodontic appliances - prevention of pit and fissure (occlusal) caries. • For the desensitisation of hypersensitive teeth as part of a treatment regimen which includes the daily use of a suitable toothpaste. Warning: “To be sold by retail on the prescription of a Dentist only”	05-06-2020
25	Paclitaxel Lipid Suspension for injection 100 mg/vial (Additional Strength)	Each vial contains: Paclitaxel100 mg	1. For the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. 2. For the adjuvant treatment of node- positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. 3. As first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, it is indicated in combination with cisplatin. 4. In combination with cisplatin, is indicated for the first-line treatment of non-small cell lung cancer in patients who are	16-06-2020

			not candidates for potentially curative surgery and/or radiation therapy. 5. For the second-line treatment of AIDS- related Kaposi's sarcoma Warning: "To be sold by retail on the prescription of a Oncologist only"	
26	Itraconazole Oral Solution 10 mg/ml (New Dosage Form)	Each ml contains: Itraconazole.....10 mg	For the Treatment of Oropharyngeal and Esophageal candidiasis Warning: "To be sold by retail on the prescription of a Specialist only"	25-06-2020
27	Bilastine Orodispersible Tablet 10 mg (New Dosage Form)	Each uncoated orodispersible tablet contains: Bilastine..... 10 mg	For symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticarial. Bilastine is indicated in children aged 6 to 11 years with a body weight of at least 20 kg	25-06-2020
28	Itraconazole 50 mg Capsule (Modified Dosage Form)	Each capsule contains: Itraconazole.....50 mg	for the treatment of Systematic aspergillosis, candidiasis, cryptococcosis, sportrichosis, paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycosis "WARNING: To be sold by retail on the prescription of a Specialist only". Caution: "This Itraconazole Capsules 50mg has equivalent bioavailability with that of itraconazole capsules 100mg. One capsule of this Itraconazole Capsule 50mg is therapeutically equivalent to one 100mg capsule of conventional Itraconazole capsules 100mg. The recommended dose of this Itraconazole Capsules 50mg is therefore half the recommended dose for conventional itraconazole capsules 100 mg. This Itraconazole Capsules 50mg and conventional Itraconazole Capsules 100mg are not interchangeable".	30-06-2020
29	Meropenem dry powder for injection 2000 mg	Each Vial contains: Meropenem Trihydrate Equivalent to Meropenem 2000mg Sodium Carbonate Equivalent to sodium (Na+0 180.4mg	<ul style="list-style-type: none"> Nosocomial Pneumonia like Hospital Acquired Pneumonia (HAP)/Ventilator Associated Pneumonia Urinary Tract Infections like Complicated Urinary Tract Infections Intra-Abdominal infection like Complicated Intra-Abdominal Infection Meningitis like Acute Meningitis Septicemia Empiric Treatment of Presumed infection in Adult Patients with Febrile Neutropenia 	02-07-2020
30	Dapagliflozin 10 mg	Each Film coated tablet contains: Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin.....10 mg	6. Dapagliflozin is indicated in adults for the treatment of heart failure with reduced ejection fraction.	03-07-2020
31	Ceftaroline fosamil powder for concentrate for solution for infusion	Each Vial contains: Ceftaroline Fosamil.....600mg L-Arginine.....395mg	For the treatment of the adults with complicated skin and soft tissue infections (Cssti)	06-07-2020

32	Nintedanib 100mg/150mg	Each soft Gelatin capsule contains: Nintedanib Ethanesulfonate equivalent to Nintedanib.....100mg/150mg	For the treatment of other chronic fibrosing interstitial Lung Diseases (ILDs) with a Progressive phenotype	09-07-2020
33	Ivabradine PR Tablets 10/15mg	Each film coated prolonged release tablet contains: Ivabradine hydrochloride equivalent to Ivabradine 10 mg / 15 mg.	For the treatment of chronic stable angina pectoris in patients with coronary artery disease and treatment of chronic heart failure.	14-07-2020
34	Paracetamol Orally Disintegrating 60/120 mg	Each Orally Disintegrating Strip contains: Paracetamol.....60mg/ 120 mg	For use in pediatric age group, for symptomatic treatment of pain and fever	14-07-2020
35	Sodium Citrate Granules 4.0 gm	Each sachet (5.6g) contains: Sodium Citrate 4.0 g	As an alkalising agent in cystitis in women	16-07-2020
36	Bedaquiline Tablet 100 mg	Each uncoated tablet contains: Bedaquiline fumarate equivalent to 100 mg of Bedaquiline	In adult (>18 years) and pediatric patients (12 years to less than 18 years of age and weighing at least 30 kg) as part of combination therapy of pulmonary tuberculosis (TB) due to multi-drug resistant Mycobacterium tuberculosis.	16-07-2020
37	Trimetazidine Hydrochloride Extended Release Capsules 80mg	Each hard gelatin capsule contains: Trimetazidine hydrochloride (as extended release pellets)... 80 mg	For the treatment of Ischaemic heart disease (angina pectoris, sequelae of infarction).	21-07-2020
38	Regorafenib Tablet 40 mg (Additional Indication)	Each film coated tablet contains: Regorafenib.....40 mg	For the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with Sorafenib Warning: "To be sold by retail on the Prescription of an Oncologist only"	03-08-2020
39	Baclofen Extended Release tablet 30mg (Additional dosage & Strength)	Each uncoated extended release tablet contains: Baclofen....30 mg	For the symptomatic treatment of neuronal spasticity due to multiple sclerosis, spinal cord, pathology & injury	04-08-2020
40	Tofacitinib Tablet 5 mg (Additional Indication)	Each film coated tablet contains: Tofacitinib citrate equivalent to tofacitinib.....5 mg	For the treatment of adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or intolerance to methotrexate or other non-biologic disease modifying antirheumatic drugs (DMARDs) Warning: "To be the prescription of a Rheumatologist or Specialist in Internal Medicine only"	04-08-2020
41	Enzalutamide 80 mg capsules (Additional strength)	Each hard gelatin capsule contains: Enzalutamide....80mg	For the treatment adults with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after Docetaxel therapy. Warning: "To be sold by retail on the Prescription of an Oncologist only"	06-08-2020
42	Oxaceprol Sustained Release Tablet 600 mg (Additional strength)	Each film coated SR tablet contains: Oxaceprol.....600 mg	Treatment of pain associated with osteoarthritis of knee in adult patients	07-08-2020

43	Olaparib 100/150 mg (Additional Indication)	Each film-coated tablets contains: Olaparib.....100mg/150 mg	Olaparib is indicated as monotherapy for the treatment of adult patients with metastatic castration-resistant prostate cancer and homologous recombination repair gene mutations (germline and/or somatic) who have progressed following a prior new hormonal agent. Warning: “To be sold by retail on the Prescription of an Oncologist only”	17-08-2020
44	Levofloxacin Dispersible Tablets 100 mg (New Dosage Foam)	Each dispersible tablet contains: Levofloxacin hemihydrate Equivalent to Levofloxacin100 mg	Indicated in combination with other anti-tuberculosis agents, for the treatment of tuberculosis caused by Mycobacterium tuberculosis in children. Warning: “To be sold by the prescription of a Medical Specialist only”	18-08-2020
45	Trihexyphenidyl Hydrochloride 1 mg (Additional strength)	Each uncoated tablet contains: Trihexyphenidyl hydrochloride1 mg	It is indicated in all forms of Parkinsonism (postencephalitic, arteriosclerotic and idiopathic). It is often useful as adjuvant therapy when treating these forms of Parkinsonism with levodopa. Trihexyphenidyl is also indicated to control extrapyramidal disorders due to central nervous system drugs such as reserpine and the phenothiazines. Warning: “To be sold by the prescription of Neurologist only”	18-08-2020
46	Olaparib 100/150 mg (Additional Indication)	Each film-coated tablets contains: Olaparib.....100mg/150 mg	Olaparib in combination with bevacizumab is indicated for the Maintenance treatment of adult patients with advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (Complete response or partial response) to first-line platinum-based chemotherapy with bevacizumab. Warning: “To be sold by retail on the Prescription of an Oncologist only”	21-08-2020
47	Ferric Carboxymaltose Solution for Injection/Infusion 20mg/vial (Additional Pack Size)	Each ml contains: Ferric Carboxymaltose equivalent to Elemental Iron.....50 mg.	For the treatment of iron deficiency in adults when oral iron preparations are ineffective or cannot be used.	27-08-2020
48	Lipid Based Tacrolimus Ointment 0.1% w/w (Additional indication)	Each gram contains: Tacrolimus Monohydrate Equivalent to Tacrolimus0.1% w/w	For the short-term and non-continuous chronic treatment of symptomatic lichen planus (oral and mucosal forms) in non-immunocompromised patients Warning: “To be the prescription of a Dermatologists only”	28-08-2020
49	Moxifloxacin Dispersible Tablets 100 mg (New Form dosage)	Each dispersible tablet contains: Moxifloxacin Hydrochloride Equivalent to Moxifloxacin 100 mg	Indicated in combination with other antituberculosis agents for the treatment of tuberculosis caused by Mycobacterium tuberculosis. as a second-line anti-mycobacterial drug when use of first line drugs is not appropriate due to resistance or intolerance	02-09-2020
50	Tapentadol Hydrochloride Nasal Spray 225 mg/ml (New Form dosage)	Each Spray (0.1 ml) contains: Tapentadol Hydrochloride 22.5 mg Benzalkonium chloride (50%) 0.02%w/v (As Preservative)	For treatment of moderated to severe post-operative pain in hospital admitted patients	02-09-2020
51	Favipiravir 800mg Tablet (Additional strength)	Each film coated tablet contains: Favipiravir 800 mg	For the treatment of patients with mild to moderate Covid-19 disease, in light of Covid 19 outbreak, for restricted emergency use in the country. “WARNING: To be sold on the prescription of medical specialist”	24-09-2020

52	Isotretinoin Capsules 8/16/24 mg (Additional Strength & Indication)	Each soft gelatin capsule contains: Isotretinoin...8mg/16mg/24mg	For the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, it is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. “Warning: To be sold by retail on the prescription of Dermatologist only”	29-09-2020
53	Brivaracetam Tablets (Additional Strength)	Each film coated tablet contains: Brivaracetam 25mg	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy	01-10-2020
54	Perampanel Tablets 2 mg/4mg/6 mg/8 mg/12 mg (Additional Indication)	Each film coated tablet contains: Perampanel 2mg/4mg/6mg/8mg/10 mg/12mg	As an adjunctive treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy 4 years of age and older “Warning: To be sold by retail on the prescription of Neurologist only”	01-10-2020
55	Acotiamide 300 mg Tablet (Additional dosage foam)	Each film coated Extended release tablet contains: Acotiamide Hydrochloride Hydrate 300mg	For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia	05-10-2020
56	Azathioprine 75 mg Tablet (Additional Strength)	Each film coated tablet contains: Azathioprine 75 mg	Indicated for facilitating the survival and function of organ transplants “Warning: To be sold by retail on the prescription of Medical Specialist only”	14-10-2020
57	Travoprost Eye Drops 0.004% w/v (Preserved with an ionic buffer system)	Each ml contains Travoprost .0004% w/v	For the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension “Warning: To be sold by retail on the prescription of Ophthalmologist only”	16-10-2020
58	Remdesivir for Injection 100 mg/vial (lyophilized) (Expansion of Indication)	Each vial contains: Remdesivir 100 mg (lyophilized)	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with moderate to severe disease. In light of Covid 19 outbreak, for restricted emergency use in the country. “Warning: To be sold by retail on the prescription of specialist for use in Hospital/Institutional Setup only”	19-10-2020
59	Lidocaine Spray 10% w/v (Additional Strength)	Each ml contains: Lidocaine 100 mg Ethanol..... 30.4% v/v Flavored Base..... q .s.	Lidocaine Spray 10% w/v is indicated for the prevention of pain associated with the following procedures: Otorhinolaryngology: Anesthesia prior to minor non-invasive procedures in the nasal cavity, pharynx and epipharynx including rhinoscopy and laryngoscopy. Obstetrics: During the final stages of delivery and before episiotomy and perineal suturing as supplementary pain control. Insertion of instruments and catheters into the respiratory and digestive tract: Provides surface anesthesia for the oropharyngeal and tracheal areas to reduce reflex activity, attenuate hemodynamic response and to facilitate insertion of the catheter or the passage of instruments during endotracheal intubation, laryngoscopy, bronchoscopy, esophagostomy and gastroscopy. Dental practice: Before minor dental procedures where local anesthesia is desired.	02-11-2020

60	Combipack OF Favipiravir Tablets (Combipack)	Each Combipack contains: Favipiravir Tablets 200 mg (2 tablets) Each film coated tablets contains: Favipiravir 200mg Favipiravir Tablets 800 mg (16 tablets) Each film coated tablets contains: Favipiravir 800mg	For restricted emergency use for the treatment of patients with mild to moderate Covid-19 disease “WARNING: To be sold on the prescription of medical specialist” which shall be in box with red background.	27-11-2020
61	Vildagliptin Sustained Release Tablets 100 mg (OROS) (Additional Strength)	Each film coated sustained release bi-layered tablet contains: Vildagliptin 100mg	As an adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes mellitus (T2DM)	15-12-2020
62	Thyroxine Sodium Tablets 112 mcg (Additional Strength)	Each uncoated tablet contains: Thyroxine Sodium112 mcg	For the treatment of hypothyroidism	17-12-2020
63	Triamcinolone Acetonide Cream 0.1% w/w (New Dosage Foam)	Each gm contains: Triamcinolone Acetonide1mg Benzyl alcohol (as preservative)2% w/w In a cream baseq.s.	Inflammatory and pruritic manifestations of corticosteroid responsive dermatoses “WARNING: To be sold by retail on the prescription of Dermatologist only”	22-12-2020
64	Palbociclib Tablets 75/100/125 mg	Each film coated tablet contains: Palbociclib75mg/100mg/125 mg	1. Palbociclib is a kinase inhibitor indicated for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) - negative advanced or metastatic breast cancer in combination with fulvestrant in women with disease progression following endocrine therapy. 2. Palbociclib is a kinase inhibitor indicated in combination with Letrozole for the treatment of postmenopausal women with estrogen receptor (ER) positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine based therapy for their metastatic disease. “WARNING: To be sold by retail on the prescription of an Oncologist only”	22-12-2020
65	Lurasidone Hydrochloride Tablets 20mg (Additional Strength)	Each film coated tablets contains: Lurasidone Hydrochloride20 mg	For treatment of patients with Schizophrenia “WARNING: To be sold by retail on the prescription Neurologist only”	24-12-2020
66	Hydrocortisone Sodium Succinate Injection (Additional Strength)	Each vial contains: Hydrocortisone Sodium Succinate (Buffered) Eq. to Hydrocortisone200 mg	Allergic states: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions. Dermatologic diseases: Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome). Endocrine disorders: Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy,	28-12-2020

			<p>mineralocorticoid supplementation is of particular importance), congenital adrenal hyperplasia, hyper calcemia associated with cancer, nonsuppurative thyroiditis. Gastrointestinal diseases: To tide the patient over a critical period of the disease in regional enteritis (systemic therapy) and ulcerative colitis. Hematologic disorders: Acquired (autoimmune) hemolytic anemia, congenital (erythroid) hypoplastic anemia (Diamond-Blackfan anemia), idiopathic thrombocytopenic purpura in adults (intravenous administration only; intramuscular administration is contraindicated), pure red cell aplasia, selected cases of secondary thrombocytopenia. Miscellaneous: Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy. Neoplastic diseases: For the palliative management of leukemias and lymphomas. Nervous System: Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor, or craniotomy. Ophthalmic diseases:</p> <p>Sympathetic ophthalmia, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids. Renal diseases: To induce diuresis or remission of proteinuria in idiopathic nephritic syndrome or that due to lupus erythematosus. Respiratory diseases:</p> <p>Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis. Rheumatic disorders:</p> <p>As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, temporal arteritis, polymyositis, and systemic lupus erythematosus</p>	
67	Saroglitazar Tablets 4mg (Additional Indication)	Each uncoated tablet contains: Saroglitazar 4 mg.	Non-Alcoholic Fatty Liver Disease (NAFLD) with comorbidities (Either Obesity, Type 2 Diabetes Mellitus, Dyslipidemia Or Metabolic Syndrome)	28-12-2020

Website Update 01-01-2021 to 31-07-2021

Sl. No.	Drug Name	Composition	Indication	Date of Approval
1	Atropine Sulfate Ophthalmic Solution USP 0.01% w/v (Additional Strength)	Each ml contains: Atropine Sulfate..... 0.1 mg Polyhexamethylene biguanide Hydrochloride.....0.05mg (As Preservative)	It is indicated to control the progression of myopia in children of 5 years and above “WARNING: To be sold by retail on the prescription of Ophthalmologist only” With the Condition to conduct phase IV Clinical trial to assess long term safety of the product.	12-01-2021
2	Colistimethate Sodium For Injection IP 3 MIU/ 4.5 MIU	(i) Colistimethate Sodium for Injection IP 3 MIU	For the treatment of some serious infections caused by Gram-negative bacteria, including those of the lower respiratory tract and urinary tract, when more commonly	15-01-2021

	(Additional Strength)	Each Vial contains Colistimethate Sodium3 000000 IU (ii) Colistimethate sodium for Injection IP 4.5 MIU Each Vial contains: Colistimethate Sodium..... 45 00000 IU	used systemic antibacterial agents may be contraindicated or may be ineffective because of bacterial resistance. “WARNING: To be sold by retail on the prescription of a Medical Specialist only”	
3	Dapagliflozin Tablets 10 mg Additional Indication	Each film-coated tablets contains: Dapagliflozin propanediol monohydrate equivalent to Dapagliflozin 10 mg	For the treatment of patients of Chronic Kidney Disease (CKD) up to Stage III (eGFR of greater than or equal to 30ml/min/1.73m2) “WARNING: To be sold by retail on the prescription of Nephrologist only”	03-02-2021
4	Brivaracetam Oral Solution 10mg/ml Additional Dosage Form	Each ml contains: Brivaracetam10mg	As adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy	03-02-2021
5	Drospirenone Tablets 4 mg Additional Strength	Each for uncoated Tablets Drospirenone..... 4 mg	Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy	15-02-2021
6	Apomorphine Hydrochloride 5 mg/ml solution for infusion in 20ml vial Apomorphine Hydrochloride 10 mg/ml solution for injection in 3ml cartridge Additional pack size & strength	Apomorphine Hydrochloride solution for infusion in 20ml vial Each ml contains: Apomorphine Hydrochloride..... 5mg Apomorphine Hydrochloride solution for injection in 3ml cartridge Each ml contains: Apomorphine Hydrochloride..... 10 mg	For the treatment of disabling motor fluctuations (“on-off” phenomena) in patients with Parkinson’s disease which persist individually titrated treatment with Levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists. “WARNING: To be sold by retail on the prescription of Neurologists only”	16-02-2021
7	Thyroxine Sodium Tablets 88 mcg / 200mcg Additional Strength	Each uncoated tablet contains: Thyroxine Sodium..... 88 mcg / 200 mcg	For the treatment of hypothyroidism	22-02-2021
8	Brivaracetam injection 50mg/5ml (10mg/ml) Additional dosage form & New route of administration	Each ml contains: Brivaracetam.....10mg	As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy	24-02-2021
9	Aripiprazole powder and solvent for prolong-release suspension for injection 300mg/vial and 400 mg/vial (Modified Dosage Form)	Each vial contains: Aripiprazole..... 300mg / 400mg (Supplied along with solvent/diluent)	Maintenance treatment of schizophrenia in adult patients stabilized with oral aripiprazole “WARNING: To be sold by retail on the prescription of an Psychiatrist only”	01-03-2021
10	Rebamipide Ophthalmic Suspension 2% w/v with Stabilized Oxychloro complex (as preservative)	Each ml contains: Rebamipide%w/v Stabilized Oxychloro Complex.....0.01% w/v (As Preservative)	Indicated for the treatment of dry eye signs and symptoms	01-03-2021
11	Pancreatin Tablets USP 200 mg (Additional Strength/New dosage form/New Indication)	Each uncoated tablet contains: Pancreatin ...200mg Equivalent to Lipase 10,440 USP units Amylase 39,150 USP units	Indicated in combination with a proton pump inhibitor in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy	01-03-2021

		Protease.....39150 USP units		
12	Pemetrexed for injection 100mg/500mg (Additional Indication)	Each vial contains: Pemetrexed Disodium equivalent to Pemetrexed.....100mg/500mg	In combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations “WARNING: To be sold by retail on the prescription of oncologist only”	08-03-2021
13	Ibuprofen solution for infusion 400mg/100ml (New Dosage Form)	Each ml contains: Ibuprofen..... 4mg	Indicated in adults for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified when other routes of administration are not possible	08-03-2021
14	Cholecalciferol oral drops 800IU/ml (Additional Strength/New dosage Form)	Each ml contains: Cholecalciferol..... 800IU	For the treatment of vitamin D3 deficiency	08-03-2021
15	Osimertinib Tablets 40mg and 80mg (Additional Indication)	Each film-coated tablets contains: Osimertinib (as mesylate)... 40 mg/80mg	Osimertinib as monotherapy is indicated for: The adjuvant treatment after complete tumour resection in patients with nonsmall cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations “WARNING: To be sold by retail on the prescription of oncologist only”	09-03-2021
16	Dolutegravir Dispersible Tablets 10mg (Additional Dosage Form)	Each Tablet contains: Dolutegravir sodium equivalent to Dolutegravir 10mg	In combination with other antiretroviral agents for the treatment of Human Immunodeficiency Virus type1 (HIV- 1) infection in adults (treatment-naïve or-experienced) and in pediatric patients (treatment-naïve or -experienced but integrase strand transfer inhibitor [INSTI]-naïve) aged at least 4 weeks and weighing at least 3 kg “WARNING: To be sold by retail on the prescription of a Specialist only”	23-03-2021
17	Sildenafil Citrate Oral Spray 12.5% w/v (Additional Dosage Form)	Each Spray (0.2ml) delivers Sildenafil citrate equivalent to Sildenafil.....25 mg	For the treatment of Erectile Dysfunction in men “WARNING: To be sold by retail on the prescription of an Urologist, Psychiatrist and Endocrinologist only”	26-03-2021
18	Dexamethasone Tablets 6 mg (Additional Strength)	Each film coated tablet contains : Dexamethasone6 mg	Dexamethasone is indicated for treatment of variety of disorders in which systemic glucocorticoids are indicated including: • Neurology: Cerebral oedema (only with symptoms of intracranial pressure evidenced by computerised tomography) caused by a primary or metastatic brain tumour, craniotomy or head injury. • Dermatology: Initial treatment of extensive, severe, acute, skin diseases responding to glucocorticoids, e.g. erythroderma, pemphigus vulgaris • Autoimmune disorders/rheumatology: Initial treatment of autoimmune disorders like systemic lupus erythematoses, in acute gouty arthritis ,acute arthritis carditis, ankylosing spondylitis ,psoriatic arthritis , Severe progressive course of active rheumatoid arthritis Severe systemic course of juvenile idiopathic arthritis (Still's disease). • Haematological disorder: Idiopathic thrombocytopenic	06-04-2021

			<p>purpura in adults.</p> <ul style="list-style-type: none"> • Oncologists only- for steroid responsive neoplastic disease like leukemias and lymphomas in adults only. 	
19	<p>Betahistine Hydrochloride Orally</p> <p>Disintegrating tablet 8 mg/16mg/24 mg</p> <p>(New Dosage Form)</p>	<p>Each Uncoated Orally Disintegrating Tablet contains:</p> <p>Betahistine Hydrochloride mg/16mg/24mg Excipients q.s.</p>	<p>Indicated for the symptomatic treatment of vertigo caused due to conditions including Menier's syndrome.</p>	06-04-2021
20	<p>Pegaspargase powder for solution for injection/ infusion</p> <p>(New Dosage Form & Indication)</p>	<p>Each vial contains:</p> <p>Pegaspargase3750 U (After reconstitution each ml contains 750U of Pegaspargase)</p>	<p>Indicated as a component of anti-neoplastic combination therapy in acute lymphoblastic leukaemia (ALL) in paediatric patients from birth to 18 years, and adult patients</p>	09-04-2201
21	<p>Drospirenone Tablets 4mg</p> <p>(New Dosage Form)</p>	<p>Each Film Coated Tablet contains:</p> <p>Drospirenone 4mg</p>	<p>Drospirenone is a Progestin intended for its use by females of reproductive potentials to prevent pregnancy</p>	22-04-2021
22	<p>Baricitinib Tablets 1mg, 2mg, & 4 mg</p> <p>(Additional Strength & Additional Indication)</p>	<p>Each Film Coated Tablet contains:</p> <p>Baricitinib....1mg/ 2mg/4 mg</p>	<p>Baricitinib, in combination with Remdesivir, for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)</p> <p>“WARNING: To be sold by retail on the prescription of specialist for use in Hospital/ Institutional set up only”</p>	01-05-2021
23	<p>Remdesivir Injection</p> <p>100mg/20 ml</p> <p>(without Cyclodextrin)</p>	<p>Each ml contains:</p> <p>Remdesivir.....5mg</p>	<p>For treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults and children hospitalized with moderate to severe disease</p> <p>“WARNING: To be sold by retail on the prescription of specialist for use in Hospital/ Institutional set up only”</p>	06-05-2201
24	<p>Favipiravir Oral suspension</p> <p>100mg/ml</p> <p>(New Dosage Form)</p>	<p>Each ml contains:</p> <p>Favipiravir..... 100mg</p>	<p>For the treatment of patients with mild to moderate Covid-19 disease</p> <p>“Warning: To be sold on prescription of medical specialist”</p>	19-05-2021
25	<p>Posaconazole Delayed-Release Tablets</p> <p>(Additional Indication)</p>	<p>Each Delayed-Release Tablets contains:</p> <p>Posaconazole..... 100mg</p>	<ul style="list-style-type: none"> • For the treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to Itraconazole and/or fluconazole for prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy. • Zygomycosis (Mucormycosis) in patients with diseases refractory to other therapy ,or or patients who are intolerant to other therapy <p>“Warning: To be sold on prescription of medical specialist”</p>	28-05-2021
26	<p>Posaconazole Gastro-Resistant Tablets 300 mg</p> <p>(Additional Strength)</p>	<p>Each Gastro-Resistant Tablet contains:</p> <p>Posaconazole.....3 00 mg</p>	<p>For prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with</p>	07-06-2021

			<p>prolonged neutropenia from chemotherapy.</p> <p>Posaconazole Gastro Resistant Tablets are indicated in patients 13 years of age and older.</p> <p>“WARNING: To be sold by retail on the prescription of a Medical Specialist only”</p>	
27	Ulinastatin for injection 200000 IU (Liquid) (Additional Strength)	<p>Each vial contains:</p> <p>Ulinastatin..... 200000 IU</p>	<ul style="list-style-type: none"> • For the treatment of severe sepsis. • For the treatment of mild and severe acute pancreatitis. 	24-06-2021
28	Imatinib Oral Solution 80 mg/ml (New Dosage Form)	<p>Each ml contains:</p> <p>Imatinib (As mesilate) 80mg</p>	<p>1. Treatment of adult and pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) integrated with chemotherapy.</p> <p>2. Treatment of adult patients with relapsed or refractory Ph+ ALL as monotherapy.</p> <p>3. Adjuvant treatment of adult patients following resection of gastro-intestinal stromal tumors (GIST), and 4. Treatment of CML in blast crisis, accelerated phase or in chronic phase after failure of interferon alpha therapy.</p> <p>“WARNING: To be sold by retail on the prescription of oncologist only”</p>	24-06-2021
29	Clozapine Tablet 12.5 mg (Additional Strength)	<p>Each uncoated tablet contains:</p> <p>Clozapine 12.5 mg</p>	<p>Indicated in the management of schizophrenic patients</p> <p>“WARNING: To be sold by retail on the prescription of Neurologist only”</p>	29-06-2021
30	Sorafenib Tablets 400mg (Additional Strength)	<p>Each film coated tablets contains :</p> <p>Sorafenib Tosylate eq. to Sorafenib...400 mg</p>	<p>For the treatment of hepatocellular carcinoma, advanced renal cell carcinoma and locally advanced or metastatic differentiated thyroid carcinoma refractory to radioactive iodine</p> <p>“WARNING: To be sold by retail on the prescription of Oncologist only”</p>	30-06-2021
31	Favipiravir Powder for Oral suspension 800mg (Additional Dosage Form)	<p>Each sachet contains:</p> <p>1.5g of Favipiravir powder contains:</p> <p>Favipiravir 800mg Excipients q.s</p>	<p>For the treatment of patients with mild to moderate Covid-19 disease</p> <p>“WARNING: To be sold on the prescription of medical specialist”</p>	06-07-2021
32	Heparin Sodium Topical Solution 1000 IU/ml (Additional Indication)	<p>Each ml contains :</p> <p>Heparin Sodium1000 IU/ml</p> <p>Absolute Alcohol.....10.00%v/v</p> <p>Topical Solution base.....q.s.</p>	<p>For Prevention of infusion associated phlebitis</p> <p>“WARNING: To be sold by retail on the prescription of Specialists only”</p>	09-07-2021
33	Pemetrexed for injection 1000mg (Lyophilized) (Additional Strength)	<p>Each vial contains:</p> <p>Pemetrexed Disodium heptahydrate IP equivalent to Pemetrexed.....1000mg</p>	<p>1. Indicated as a monotherapy for the maintenance treatment of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy. First line treatment Should be a platinum doublet with gemcitabine, paclitaxel or docetaxel.</p> <p>2. In combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly</p>	16-07-2021

			<p>squamous cell histology.</p> <p>3. As monotherapy for the second-line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.</p> <p>4. As monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has to progressed immediately following platinum based chemotherapy.</p> <p>“WARNING: To be sold by retail on the prescription of oncologist only”</p>	
34	Acetyl Salicylic Acid Effervescent Tablets 500 mg (Additional Dosage Foam)	Each Effervescent tablet contains: Acetyl Salicylic Acid ... 500 mg	Analgesic & Anti pyretic	16-07-2021
35	Pentosan polysulfate sodium sterile solution for intravesical instillation 10 mg/ml (30ml) (Additional Dosage form & Route of administration)	Each ml contains: Pentosan Polysulfate Sodium.....10mg	For intravesical treatment of the bladder pain syndrome/interstitial cystitis “WARNING: To be sold by retail on the prescription of a Specialist only”	16-07-2021
36	Amikacin Injection 750mg/3ml & 1000 mg/4ml (Additional pack size /Additional Strength)	Amikacin Injection IP 750 mg Each 3ml contains: Amikacin Sulphate IP Equivalent to Amikacin.....750 mg Water for Injections IP..... q.s Methylparaben IP.....0.04w/v Propylparaben IP.....0.01w/v (As preservatives) (Suitable buffering agent and antioxidant added) Amikacin Injection IP 1000 mg Each 4ml contains: Amikacin Sulphate IP Equivalent to Amikacin1000 mg Water for Injections IP..... q.s Methylparaben IP.....0.04w/v Propylparaben IP.....0.01w/v (As preservatives) (Suitable buffering agent and antioxidant added)	Amikacin Injection is indicated in the treatment of serious infections due to Amikacin sensitive organisms “WARNING: To be sold by retail on the prescription of a Specialist only”	23-07-2021
37	Riboflavin Sodium Phosphate IP eq. to Riboflavin 0.1 % w/v with Hypromellose Ophthalmic Solution in PFS (Pack Size is 3.0ml) (Additional Pack Size)	Each ml contains: Riboflavin Sodium Phosphate IP Eq. to Riboflavin.....0.1% w/v Hypromellose I.P... ..%w/v	To treat keratoconus and corneal ectasia following refractive surgery	27-07-2021
38	Amorolfine Lotion 0.25% w/v (Additional Dosage Form)	Each ml contains: Amorolfine Hydrochloride Equivalent to Amorolfine.....0.25% w/v	For the treatment of dermatomycosis caused by dermatophytes, cutaneous candidiasis and pityriasis versicolor “WARNING: To be sold by retail on the prescription of an Dermatologist only”	29-07-2021

39	Silodosin Tablet 8 mg (Additional Dosage Form)	Each film coated tablets contains : Silodosin...8 mg	For the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) in adults only “WARNING: To be sold by retail on the prescription of a Urologist only”	30-07-2021
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