

## IST OF APPROVED DRUG FROM 01.01.08 TO 31.12.08

S. No.	Drug Name	Indication	Approval Date
1	Me-salicylate 30% + Menthol 10% + camphor 4% Cream	For temporary relief from pain, swelling & inflammation due to musculoskeletal disorder	29.11.07
2	Voglibose 0.2mg/0.3mg tablet (Mouth dissolving)	For improvement of parantial hyperphemia in diabetis mellitus only. When diet and/or exercise or oral, hypoglyceamic drug or insulin preparation in addition to diet and or exercise do not result in adequate glycemic control.	28.12.07
3	Hydroxychloroquine 400mg tablets (Additional Strength)	Same as Approved	31.01.08
4	ISMN 30mg SR + Metoprolol Succinate equivalent to metoprolol tartrate 25mg/50mg tablets (Additional Strength)	Same as Approved	02.01.08
5	Halobetasol 0.05% + Clotrimazole 1.0% cream	For the treatment of steroid responsive fungal infections including eczema and psoriasis	04.01.08
6	Citicholine Syrup 750mg/5ml	For the treatment of disturbance of consciousness resulting from head injuries, brain operation and acute stage of cerebral infarction in adults only	04.01.08
7	Levodopa 200mg + Carbidopa 50mg C.R. tablet	For Parkinson's Disease	08.01.08
8	Nanocrystalline Silver Gel 0.002%	For the treatment of burns and wound infections	04.01.08
9	Cinitapride (as hydrogen tartrate) 1mg tablet	For the treatment of gastroesophageal reflux	04.01.08

		disease and functional inconveniences of the gastrointestinal motility	
10	Tenofovir disoproxil fumarate 300mg + Lamivudine 300mg tablet	For the treatment of adult patients with HIV infection	07.01.08
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	07.01.08
12	D-Trans Fentanyl Metrix system (12mcg/hr.) (Additional Strength)	Same as Approved	07.01.08
13	Ceftazidime 500mg + Tobramycin 60mg per vial (Injection)	For the treatment of lower respiratory tract infection caused by pseudomonas aeruginosa	08.01.08
14	Atazanavir 300mg capsules (Additional strength)	Same as approved	08.01.08
15	Ertapenem for injection 1gm/vial (additional indication)	For the prophylaxis of surgical site infections following elective colorectal surgery	15.01.08
16	Vildagliptin Tablets 50mg/100mg	As an adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes mellitus	18.01.08
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	18.01.08
18	Smatriptan (as succinate ) 50mg + Naproxen sodium 550mg tablets	For the treatment of acute migraine	22.01.08

19	Sodium Valproate 666mg + valproic acid 290mg equivalent as sodium valproate 1000mg C.R. tablet (Additional Strength)	Same as Approved	24.01.08
20	Cefepime (as hydrochloride) 2000/1000/500mg + Sulbactam (as sodium) 1000/500/250mg per vial of injection	For serious CRTI, uncomplicated and complicated UTI, Uncomplicated skin & skin structure, infection acute exacerbation of chronic bronchitis & intraabdominal infection.	24.01.08
21	Paclitaxel Nanoparticle Solution for Injection 20mg/ml (Additional indication)	Ovarian cancer, non-small cell lung cancer and AIDS related Kaposi Sarcoma	22.01.08
22	Sorafenib tablets 200mg (Additional Indication)	For hepatocellular Carcenoma	22.01.08
23	Zanamavir 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)	22.01.08
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	23.01.08
25	Combikit 4 tablets of Alendronate sodium trihydrate equivalent to Alendronic acid 70mg each + 24 tablets of Calcium carbonate 1250mg (equivalent to 500mg Calcium) + cholecalciferol-250IU	For the treatment of osteoporosis in post-menopausal women	23.01.08
26	Aceclofenac injection 150mg/ml	For short term treatment of pain due to post operative and post traumatic cases	23.01.08
27	Atorvastatin 10mg + Fenofibrate 80mg tablet (Additional Indication)	For the treatment of combined hyperlipidemia in patients with normal	25.01.08

		hepatic and renal functions.	
28	Sodium Valproate 499.5mg + Valproic acid 217.5mg equivalent as sodium valproate- 750mg CR tablet (Additional Strength)	Same as Approved	24.01.08
29	Diclofenac 50mg + Serratiopeptidase 10mg enteric coated tablet	For the treatment of acute pain in adults	24.01.08
30	Gabapentin 100mg + methylcobalamin 500mcg tablets (Additional Strength)	Same as Approved	24.01.08
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, Septicemia, bacteremia	24.01.08
32	Metformin HCl ER 500mg + Fenofibrate 80mg/160mg tablet	For the treatment of Type-II diabetes associated with mixed dyslipidemia	25.01.08
33	Salicylic acid 10mg/20mg (Foaming facewash solution)	For the treatment of acne vulgaris	28.01.08
34	Ozagrel Hcl. Tablets 100mg/200mg	For the treatment of bronchial asthma	28.01.08
35	Rivastigmine transdermal patch (each patch of 5m <sup>2</sup> , 10m <sup>2</sup> , 15m <sup>2</sup> & 20m <sup>2</sup> contain Rivastigmine base 9/18/27/36mg respectively)	For the treatment of patients with mild to moderately severe dementia of the Alzheimer type and dementia associated with Parkinsons disease	28.01.08
36	Daptomycin powder for concentrate for solution for infusion (350mg/500mg per vial)	For the treatment of complicated skin and skin structure infections and for staphylococcus aureus bloodstream infections (bacteremia)	28.01.08

37	Dextromethorphan Orodispersible strip 5.5mg/11mg	For the relief of persistent dry irritating cough in adult patients only	28.01.08
38	Diclofenac sodium 50mg + Dicyclomine HCl 20mg per ml of injection	For the treatment of acute colicky pain in adults	28.01.08
39	Travoprost 40mcg + Timolol (as Maleate) 5mg 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	28.01.08
40	Amoxicillin 250mg/125mg + Cloxacillin 250mg/125mg + Lactic Acid Bacillus 1.7 Billion spores	For RTI, SRS of tissue infection, bone & joint infection, ENT infection in adults prone to antibiotic associated diarrhoea	30.01.08
41	Amoxicillin 250mg + Lacto- Bacillus 1.7 billion Spores	For RTI, SRS of tissue infection, bone & joint infection, ENT infection in adults prone to antibiotic associated diarrhoea	31.01.08
42	Mecobalamin 1500mcg + Alpha Lipoic Acid 100mg + Benfothiamine 15mg + B6 3mg + Calcium Pantothenate 25mg + Folic Acid 1.5mg + Zinc oxide 22.5mg + Chromium picolinate 65mcg + Inositol 10mcg + Lutein 5mg capsule	For Vitamins and Minerals deficiency states in adult patients	30.01.08
43	Methylcobalamine 750mcg + Alpha lipoic acid 100mg + Benfothiamine 7.5mg + B6 1.5mg + Calcium pantothenate 25mg + Nicotinamide 50mg + Folic acid 0.75mg capsule	For Vitamins and Minerals deficiency states in adult patients	30.01.08

44	Mecobalamin 500mcg + Alpha Lipoic Acid 200mg + Benfotiamin 10mg + Pyridoxine 3mg + Biotin 5mg + Folic acid 1.5mg capsule	For Vitamins deficiency states in adult patients	30.01.08
45	Amoxicillin 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	30.01.08
46	Tiotropium (as Tiotropium Bromide Monohydrate) 18mcg + Formoterol Fumarate Dihydro. 12mcg + Ciclesomide 400mcg per capsules	As 3rd line treatment of sever cases of COPD when monotherapy and second line therapy with two drugs do not respond adequately	31.01.08
47	Metoprolol Succinate Equivalent to Metoprolol Tartrate [ER 25/50mg] + Atorvastatin (As calcium) 10mg tablets	For the treatment of patient with both essential hypertension and hypercholesterolemia	28.01.08
48	Levocetirizine Di HCl Dispersible tablet 5mg/10mg (New Dosage form)	For allergic rhinitis & chronic urticaria	28.01.08
49	Oseltamivir 30mg & 45mg Capsules (Additional Strength)	Same as Approved	28.01.08
50	Fondaparinux Sodium injection (Additional Indication)	Treatment of acute coronary syndrome (ACS) with and without ST-segment elevation	28.01.08
51	Camostat Mesylate tablets 100mg	For remission of acute symptoms of chronic pancreatitis and post-operative reflux esophagitis	29.01.08
52	Hyaluronic Acid Salt 25mg + Cross-Linked Hyaluronic acid 25mg per ml in prefilled syringe	For intradermal implantation and facial soft tissue augmentation	30.01.08
53	Ursodeoxycholic acid tablets 600mg	For the treatment of patients with chronic cholestatic liver disease	30.01.08

54	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	30.01.08
55	Beclomethasone Dipropionate 0.25mg + Econazole 10mg + Neomycin 5mg per gm of Cream	For the topical treatment of bacterial and fungal infections	30.01.08
56	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 sulfonylurea or a combination of metformin and a sulfonylureas	30.01.08
57	Diclofenac Sodium 50mg + Paracetamol 500mg tablets	For the symptomatic treatment of acute pain and inflammation in patients with osteoarthritis, rheumatoid arthritis and ankylosing spondylitis	30.01.08
58	Gabapentin SR 600mg tablets	As adjunctive therapy in the treatment of partial seizures of epilepsy	30.01.08
59	Memantine 5mg /10mg + Donepezil 5mg Tablets	For moderate to severe Alzheimer's disease	31.01.08
60	Doxifluridine Capsules 100mg/200mg	For carcinoma of the stomach, colon, rectum, breast, uterine, cervix and bladder	31.01.08
61	Haemodialysis Powder/Liquid Form containing citrate	For use for patients being treated by hemodialysis	31.01.08

62	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	31.01.08
63	Cimetropium Bromide tablet 50mg	For the treatment of irritable bowel syndrome	31.01.08
64	CyclobenzaprineHcl. Tablets 5mg/10mg	As adjunct to rest and physical therapy for relief of muscle spasm associated with acute painful musculoskeletal conditions	31.01.08
65	Sertaconazole Nitrate Cream 2%,	For the topical treatment of the superficial mycosis like dermatophytosis	31.01.08
66	Cefpodoxime 50mg + Clavulanic acid 31.25mg dispersible tablet & dry syrup (Additional strength)	Same as Approved	31.01.08
67	Darifenacin (as hydrobromide) 7.5mg/15mg ER tablets	For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency and frequency	31.01.08
68	Amoxicillin 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	31.01.08
69	Halobetasol 0.5mg + Miconazole 20mg per gram Cream	For steroid responsive dermatoses associated with superficial fungal infection of skin	31.01.08
70	Montelukast 10mg + Levocetirizine 5mg film coated tablets	For the treatment of allergic rhinitis in adults only	31.01.08

71	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	31.01.08
72	Phenylephrine 5mg + Chlorpheniramine maleate 0.5mg + Paracetamol 125mg + sodium citrate 60mg + Menthol 1mg (per 5ml) Syrup	For the treatment of common cold and cough associated with fever	31.01.08
73	Diclofenac Sodium 100mg (SR Pellets) + Rabeprazole Sodium 20mg (E.C Pellets) Capsules	For treatment of painful inflammatory conditions associated with gastroduodenal ulcers	31.01.08
74	Ciclesonide 160mcg/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	31.01.08
75	VSL # (Combination of lactic acid bacteria (VSL # 3)	For the treatment of irritable bowel syndrome	31.01.08
76	Clostimethate Sodium of 1,00,000IU 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	31.01.08
77	Ramipril 5mg + HCTZ 12.5mg tablets (Additional Strength)	Same as Approved	20.02.08
78	Metronidazole CR tablet 600mg	For the treatment of amoebiasis, urogenital trichomoniasis & giardiasis	21.02.08
79	Quetiapine fumarate SR tablets	for the additional indication "acute manic episode associated with bipolar disorder	21.02.08

80	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	25.02.08
81	Euphorbia Prostrata Dry Extract (ethanolic 80% (v/v) (35-70) :100mg tablet	For the treatment of haemorrhoid	29.02.08
82	Amtolmetin Guacil tablets 600mg	For the treatment of osteoarthritis & rheumatoid arthritis	07.03.08
83	Brimonidine Tartrate Ophthalmic solution 0.1% (with purite as preservation 0.005%) (additional strength)	For lowering of IOP in patients with open angle glaucoma ocular hypertension	07.03.08
84	Methoxsalen USP-20mg Tablet	1:- For repigmentation of idiopathic vitiligo alongwith phototherapy. 2:- For symptomatic control of severe, recalcitrant, disabling psoriasis in conjunction with phototherapy	07.03.08
85	Cefditoren pivoxil 400mg tablets (Additional Strength)	Same as Approved	11.03.08
86	Doxofylline ER tablets 400mg/800mg (addl. Strength)	For the treatment of bronchial asthma & COPD in adults	12.03.08
87	Betamethasone 0.05% +Miconazole 2% Cream	For the treatment of steroid responsive dermatoses associated with superficial fungal infections of the skin	12.03.08
88	Premetrxed disodium injection 100mg/vial (Additional Strength)	Same as Approved	12.03.08

89	Omeprazole 20mg/40mg + Sodium bicarbonate 1680mg per sachet powder for oral suspension	For gastric ulcer, duodenal ulcer, and GERD	12.03.08
90	Mecobalamin 1000mcg+ Alpha Lipoic Acid 200mg+ vitamin B6 3mg + Folic Acid 1.5mg+ Inositol 100mg + Benfotiamine 100mg capsule	For the treatment of diabetic neuropathy	19.03.08
91	ISMN 30mg SR + Atenolol 50mg tablets (Additional Strength)	Same as Approved	19.03.08
92	Temozolamide capsules 140mg/180mg (Addl. Strength)	Same as Approved	31.03.08
93	Amisulpiride 300mg tablets (Additional Strength)	Same as Approved	20.03.08
94	Nifedipine SR Tablets 10mg/20mg	For the treatment of essential hypertension	24.03.08
95	Ambroxol HCl. 15mg + Guiphenesin 50mg + Terbutalin sulphate 1.25mg + Menthol 2.5mg per 5 ml of syrup	For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis	26.03.08
96	Ambroxol HCl 30mg + Guaiphenesin 100mg + Terbutaline sulphate 2.5mg per 10ml Syrup	For the symptomatic relief of bronchospasm in bronchial asthma & chronic bronchitis	26.03.08
97	Boswellia Serrata 0.05gm/gm of Cream	For the treatment of mild to moderate psoriasis	28.03.08
98	Etoricoxib injection 90mg/ml	For short term use in acute painful condition in adults only	28.03.08
99	Drospirenone 3mg + Ethinyl estradiol 0.02mg tablets (Additional Strength)	Oral contraceptive in women	28.03.08
100	Nimesulide 100mg ER + Levocetirizine HCl 5mg Tablets	For symptomatic treatment of acute rhinosinusitis	28.03.08

101	Dexketoprofen (as Trometamol ) tablets 12.5mg/25mg	For the treatment of mild to moderate pain, such as dental pain, dysmenorrhoea & musculoskeletal pain	28.03.08
102	Nepafenac Ophthalmic suspension (1mg/ml)	For the treatment of pain and inflammation associated with cataract surgery	31.03.08
103	Hylan GF 20 Injection (Synvisc) (Additional Indication)	For pain management in patients suffering with osteoarthritis of the knee, hip, shoulder and ankle	31.03.08
104	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	31.03.08
105	Methylcobalamin 1000mcg + Pyridoxine Hcl IP 100mg + Nicotinamide IP 100mg + D-Panthenol IP 50mg per 2 ml of injection	For peripheral neuropathy	31.03.08
106	Lamivudine 20mg + Stavudine 5mg dispersible tablets (Additional Sg strength)	Same as Approved	01.04.08
107	Nicardipine Hcl. Injection 2.5mg/ml	For short-term treatment of hypertension when oral therapy is not feasible or not desirable	07.04.08
108	Diclofenac Potassium 50mg + Serratiopeptidase (as enteric coated pellets) 15mg capsules (Additional Strength)	For the treatment of acute pain in adults	08.04.08
109	Diacerin 50mg + Aceclofenac 100mg tablets	For the treatment of adult patients with osteoarthritis of knee and or hip joints	11.04.08

110	Rabeprazole sodium Enteric coated pellets 15.4% w/w (20mg/129.83mg)	Same as Approved	16.04.08
111	Live freeze-dried lactic acid bacteria and bifidobacteria capsules	For the treatment of irritable bowel syndrome	10.04.08
112	Miltefosin Capsule 10mg/50mg (Additional Indication)	Treatment of cutaneous leishmaniasis	16.04.08
113	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)	16.04.08
114	Diacerin 50mg + Glucosamine sulphate 500mg tablets.	For the treatment of adult patients with osteoarthritis of knee and hip joints	21.04.08
115	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	22.04.08
116	Fluconazole Dispersible tablets 50mg	For the treatment of systemic candidiasis, mucosal candidiasis, prevention of fungal infections in patients with malignancy	22.04.08
117	Lenalidomide Capsule 5mg/10mg/15mg/25mg (Additional Indication)	In combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy	22.04.08
118	Sitagliptin ( As Phosphate) 50mg + Metformin Hcl. 500mg/1000mg Film coated tablets	As an adjunct to diet & exercise to improve glycemic control in	28.04.08

		patients with type-two diabetes mellitus	
119	Lansoprazole for injection 30mg/vial	For short term treatment of erosive esophagitis when patients are unable to take the oral formulation	28.04.08
120	Naproxen Suspension 125mg/5ml	For the treatment of RA in children 5 years of age and above	28.04.08
121	Sevelamer Carbonate 400mg/800mg tablets & sachet 400mg/800mg	For control of serum phosphorus in patients with chronic kidney disease on dialysis	28.04.08
122	Rabeprazole Sodium (With Sodium bicarbonate as buffer) 10mg/20mg tablets	For the treatment of gastric ulcer, duodenal ulcer, Zollinger Ellison Syndrome and GERD	28.04.08
123	Pantoprazole Sodium (With Sodium bicarbonate as buffer) 20mg/40mg tablets	For the treatment of gastric ulcer, duodenal ulcer, Zollinger Ellison Syndrome and GERD	28.04.08
124	Cefdinir 250mg dispersible tablets & oral suspension 250mg/5ml	For the treatment of community acquired pneumonia, acute exacerbation of chronic bronchitis, uncomplicated skin and skin structure infection, Pharyngitis/tonsillitis	29.04.08
125	Pregabalin capsules (Addl. Indication)	management of fibromyalgia syndrome	29.04.08
126	Pregabalin 75mg/150mg + Methylcobalamin 750mcg capsules (Additional Strength)	Same as Approved	08.05.08
127	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	08.05.08

		controlled on monotherapy .	
128	Desmopriession lyophilisate Oral tablets 60mcg/120mcg/240mcg per tablets	For diabetes insipidus and nocturnal emuresis	08.05.08
129	Losartan Potassium 25mcg + Amlodipine (as besylate) 5mg tablets. (Additional Strength)	Same as Approved	14.05.08
130	Lecithin Liquid (each 5 ml contains lecithin 500mg equivalent to essential phospholipids 250mg)	For alcoholic liver disease, drug induced hepatitis	14.05.08
131	Halobetasol 0.05% + Salicylic acid 6% Ointment (additional Strength)	For the treatment of plaque psoriasis	14.05.08
132	Benzoyl Peroxide Medicated Solution (each textured pad contains 4.5%/6.5%/8.5% of solution)	For the topical treatment of acne vulgaris	14.05.08
133	Deflazocort 24mg tablets (Additional strength)	Same as Approved	14.05.08
134	Sodium Chondroitin sulfate 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	14.05.08
135	Esomeprazole (with Sodium bicarbonate as buffer) 20mg/40mg tablets	For the treatment of GERD, gastric and duodenal ulcer, Zollinger-Ellison syndrome	14.05.08
136	Telmisartan 40 mg + Atorvastatin (as calcium) 10 mg Tablets	For coexisting essential hypertension & hyperlipidemia	22.05.08
137	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	22.05.08
138	Metolazone 2.5mg + Losartan Potassium 25mg/50mg tablets	For hypertension in patients whose blood	28.05.08

		pressure is not adequately controlled in monotherapy	
139	Metolazone 2.5mg + Ramipril 2.5mg/5mg	For essential hypertension in adult patients whose blood pressure is not adequately controlled on monotherapy	28.05.08
140	Doxercalciferol 0.5mcg/2.5mcg Soft Gelatin capsules	For the treatment of secondary hyperthyroidism in patients with chronic kidney disease on dialysis	29.05.08
141	Acebrophylline capsules 100mg	For the treatment of adult patients with chronic obstructive pulmonary disease and bronchial asthma	29.05.08
142	Sofalcone Capsule (100mg/50mg)	For the treatment of gastric ulcer and management of gastric mucosal lesions (erosion, hemorrhage, redness or edema) associated with acute gastritis or acute exacerbation of chronic gastritis	02.06.08
143	S(+) Etodolac ER tablets 200mg/300mg	For the relief of pain and inflammation in patients with rheumatoid arthritis and osteoarthritis	02.06.08
144	Diclofenac Sodium 50mg + Codeine Phosphate 50mg tablets	For the treatment of adult patients with signs & symptoms of acute painful conditions	02.06.08
145	Sodium Hyaluronate injectable gel (each 0.6ml. 1ml pre filled syringe contains, sodium Hyaluronate 20mg/ml, 22.5mg/ml)	For intradermal implantation and facial soft tissue augmentation	03.06.08
146	Amphotericin B Lipid suspension injection (25mg/vial) with lipid suspension	For invasive fungal infection in patients who are refractory to or	03.06.08

		intolerant of conventional amphotericin B therapy	
147	Dexrabeprazole 10mg (EC) + Domperidone 30mg SR Capsules	For the treatment of Gastroesophageal Reflux Disease (GERD) in patients not responding to dexrabeprazole alone	09.06.08
148	Thiocolchicoside 4mg/8mg + Ketoprofen 50mg/100mg tablets	For acute low back pain & other musculoskeletal painful and inflammatory condition in adults	11.06.08
149	Cefotaxime sodium + Sulbactam sodium for injection (Additional Indication)	For the treatment of lower respiratory tract infection in children	24.06.08
150	Artemether 40mg/80mg + Lumefantrine 240mg/480mg tablets (additional Strength)	Same as Approved	24.06.08
151	Mecobalamin 0.5mg+ Alpha Lipoic Acid 100mg+ Benfotiamin100mg + Pyridoxine 50mg tablets	For the treatment of diabetic Neuropathy	03.07.08
152	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	03.07.08
153	Methylcobalamin 1500mcg + Alpha Lipoic Acid 200mg + Benfotiamine 50mg + Vit B6 3mg + Biotin 5mg + Folic Acid 1.5mg capsule	For the treatment of diabetic Neuropathy	04.07.08
154	Amino Acid, Glucose Parental Solution (Solution for intravenous infusion)	Indicated to meet daily requirement of nitrogen (amino acids), energy (glucose) for patients needing parental Nutrition	08.07.08

155	Temoporfin 1mg/ml Injection (Additional Strength)	Same as Approved	08.07.08
156	Pazufloxacin Mesylate i.v. infusion 300mg/100ml & 500mg/100ml	For the treatment of RTI, UTI and abdominal infections in adults	09.07.08
157	Metoprolol ER + Amlodipine tablets (Additional Indication)	For coronary artery disease/ischaemic heart disease	16.07.08
158	Fenofibril Disoproxil fumarate 300mg + Lamivudine 300mg + Efavirenz 600mg tablets		18.07.08
159	Vildagliptin 50mg/50mg/50mg + Metformin Hcl 500mg +850mg +1000mg tablets	For the treatment of type_II diabetes mellitus when single drug therapy alongwith diet, exercise do not result in adequate glycemic control	21.07.08
160	Testosterone Undecanoate 250mg/ml Injection	For Testosterone replacement therapy of male hypogonadism when testosterone deficiency has been confirmed by clinical feature or biochemical tests	22.07.08
161	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 methotixate or TNF antagonists	22.07.08
162	Actarit 100mg Tablets	For the treatment of rheumatoid arthritis patients	22.07.08
163	Tenofovir Fumarate 300mg + Lamivudine 300mg + Efavirenz 600mg Tablets	For the treatment of HIV infection in adults	23.07.08
164	Bacillus Clausii Spores (2 Billion) Capsules (additional dosage form)	Same as Approved	23.07.08

165	Gatifloxacin 0.3% + Ketorolac Tramthamine 0.4% eye Drop	For reduction of part operative inflammatory condition of eyes	24.07.08
166	Ketorolac Tromethamine 4mg + Gatifloxacin 3mg Eye Drops	For the reduction of post operative inflammatory conditions of the eye	24.07.08
167	Cefadroxyl (as monohydrate) 125mg + Clavulanic acid (as potassium) 31.25 per 5ml Syrup (Additional strength)	Same as Approved	25.07.08
168	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	05.08.08
169	Artemether + Lumefantrine Dispersible tablet (40/80mg + 240/480mg ) (Additional Strength)	Same as approved	05.08.08
170	Ceftazidime + Tobramycin injection (1gm + 120mg) (Additional Strength)	Same as approved	05.08.08
171	Olopatadine Nasal Spray (0.6%)	For the relief of the symptoms of seasonal allergic rhinitis in patients 12 years of age and older	05.08.08
172	Loxoprofen Sodium tablet (60mg)	For the symptomatic treatment of pain and inflammation condition in patients with osteoarthritis	14.08.08
173	Dexibuprofen Suspension 50mg/5ml	For the treatment of mild to moderate pain, reduction of fever	14.08.08
174	Bromfenac Sodium Eye Drop (0.09%)	For the treatment of postoperative inflammation & reduction of postoperative ocular pain in patients who have undergone cataract extraction	14.08.08

175	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	18.08.08
176	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	18.08.08
177	Ambroxol + loratadine + Guaifenesin Syrup (30mg + 5mg + 50mg per 5ml)	For the treatment of productive cough	18.08.08
178	Ferrous Ascorbate + Folic Acid + Zinc FC Tablets (100mg + 1.5 mg + 22.5 mg)	For the treatment of iron deficiency anaemia	18.08.08
179	Cyclobenzaprine 7.5mg tablets (Additional Strength)	Same as approved	18.08.08
180	S-Metoprolol Succinate Oral Solution (Each MI contains: S-Metoprolol Succinate 9.5mg equal to S-Metoprolol Tartrate 10mg)	For the treatment of haemo-dynamically stably patients with definite or suspected acute Myocardial Infarction to reduce cardio-vascular mortality.	19.08.08
181	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	23.08.08

182	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	25.08.08
183	Sodium Chondroitin Sulphate + Sodium Hyaluronate injection (40mg + not more than 17mg per ml)	Same as approved	25.08.08
184	Metolazone + Spironolactone FC Tablets (2.5/5mg + 50mg)	For the treatment of oedema associated with congestive heart failure, cirrhosis and nephritic syndrome	25.08.08
185	Tretinoin Microsphere Gel (0.1% W/V)	For topical treatment of acne vulgaris	26.08.08
186	Misoprostol 50Mcg tablet (Additional Strength)	Same as approved	26.08.08
187	Ferrous Ascorbate + Folic Acid Suspension (Equiv. to elemental iron 30mg + 550mcg per 5ml) (New Dosage Form)	Same as approved	27.08.08
188	Guaiphenesin ER Tablet (600mg)	For the treatment of productive cough accompanied by phlegm	28.08.08
189	Clopidogrel 300mg Tablet (addl. Strength)	As approved	02.09.08
190	Capecitabine 150/500mg Tablets (addl. Indication)	For the treatment of patients with metastatic colorectal cancer	02.09.08
191	Lopinavir + Ritonavir (100 + 25mg) Tablets (additional strength)	For the treatment of patients with HIV infection	08.09.08
192	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	13.09.08

		taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated.	
193	Halometasone (as monohydrate ) 0.05% Cream	For the relief of inflammatory and pruritic manifestation of non-infected corticosteroid responsive dermatoses like eczema	13.09.08
194	Calcium and Magnesium 24% (Veterinary) injectable solution.	For the treatment of milk fever, hypocalcaemia tetanias and disorders of calcium metabolism in dairy cattle.	13.09.08
195	Telmisartan + Ramipril (40mg + 2.5mg ) Tablets (Additional Strength)	for the treatment of essential hypertension	15.09.08
196	Drotaverine + Aceclofenac (80mg + 100mg) Tablets	For the treatment of adult patients with muscular pain associated with spasm	15.09.08
197	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	15.09.08
198	Olmesartan + Ramipril (40mg + 5mg) tablets (Additional Strength)	for the treatment of essential hypertension	15.09.08
199	Fluconazole + Zinc Pyrethron (Each 30/60ml bottle contains: 2% + 1%) Lotion	For the treatment of seborrhoeic dermatitis	15.09.08
200	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	16.09.08

		damages & chronic cerebral vascular injuries in senile dementia.	
201	Montelukast Suspension 5mg/5ml	1. For the treatment of Prophylaxis & chronic treatment of Asthma in Pediatrics patients 12 months of age & older. 2. 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.	16.09.08
202	Etoricoxib roll on Topical Solution 1% v/v	For the treatment of pain, swelling & inflammatory conditions due to arthritis.	16.09.08
203	Risedronate Sodium 150mg Tablet (Additional Strength)	As already approved	16.09.08
204	Levosulpiride Inj. 25mg/ml, 2ml	For the treatment of depression and schizophrenia in adults when oral therapy is not possible	26.09.08
205	Paliperidone ER Tablet 3mg / 6mg / 9mg	For the acute and maintenance treatment of schizophrenia	26.09.08
206	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	26.09.08
207	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	26.09.08

		staphylococcus aureus, Streptococcus dysgalactiae, and Streptococcus uberis.	
208	Ceftiofur HCl Suspension (as HCl salt) ----125mg (veterinary)	For treatment of clinical mastitis in lactating dairy cattle associated with coagulase- negative staphylococci, Streptococcus dysgalactiae, and Escherichia coli.	26.09.08
209	Nitrofurantoin SR Tab. 100mg	For the treatment of acute uncomplicated urinary tract infections (acute cystitis) caused by susceptible strains of Escherichia coli or Staphylococcus saprophyticus	26.09.08
210	Tolperisone HCl Tablet 50 / 100 / 150mg	For the relief of painful muscle spasms of the skeletal musculature	26.09.08
211	Etoricoxib + PCM (60mg + 500mg) Tablets	For the short term use in acute painful and inflammatory condition	30.09.08
212	Citicoline Oral Drops	For the treatment of disturbance of consciousness resulting from head injuries, brain operation & acute stage of cerebral infraction in adult.	30.09.08
213	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	30.09.08

214	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)	30.09.08
215	Artemether + Lumefantrine (80mg + 480mg/5ml) Dry syrup	for the treatment of chloroquine resistant/multidrug resistant on complicated malaria	30.09.08
216	Cabergoline 1mg Tablets (Additional indication)	For the treatment of hyperprolactinemia and inhibition of lactation.	01.10.08
217	Pemetrexed disodium 500mg / 100mg powder for sol. (Addl.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	08.10.08
218	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 clostridium perfringens (necrotic enteritis, wet litter, cholangiohepatitis), the prevention and treatment of ornithobacterium rhinotacheale (ORT)	08.10.08
219	Bortezomib inj.3.5mg/vial (Additional Indication)	Treatment of patients with multiple myeloma	09.10.08
220	Sertaconazole Nitrate Vaginal Tab.500mg	For the treatment of vulvo-vaginal candidiasis in women	09.10.08

221	Fosfomycin Tromethamine Sachet 3gms	For the treatment of uncomplicated urinary tract infections (acute cystitis) in women due to susceptible strains of E.Coli and Entereococcus faecalis	09.10.08
222	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	09.10.08
223	Eprosartan Mesylate 400 mg / 600mg Tablets	For the treatment of essential hypertension	11.10.08
224	Tretinoine Gel as Micro Sphere 0.04% % 0.1%	For topical treatment of Acne vulgaris.	14.10.08
225	Hydroxychloroquine Sulphate (Additional indication )	For the treatment of systemic lupus erythematosus	17.10.08
226	Budesonide + Formoterol (80/160mcg + 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	17.10.08
227	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.	21.10.08
228	Diclofenac + Thiocolchicoside (50mg (EC) + 8mg) Capsules	For the treatment of acute inflammation conditions associated with spasm in adults only	21.10.08
229	Adapalene 0.1% + Benzoyl Peroxide 2.5% gel	For the treatment of acne vulgaris	24.10.08

230	Aceclofenac Roll - On 1%	For the treatment of acute musculoskeletal pain in patients	24.10.08
231	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.	31.10.08
232	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.	03.11.08
233	Calcitriol + Calcium + Zinc (0.25mcg + 200mg + 7.5mg) Capsules	For the treatment of hypocalcaemia and/or osteoporosis	04.11.08
234	Atazanavir + Ritonavir(300mg + 100mg) FC Tablets	For the treatment of patients with HIV infection	04.11.08
235	Timolol Maleate SR Eye Drops 5.0mg / ml	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open angle glaucoma.	08.11.08
236	Rosuvastatin Calcium tablets 5/10/20/40mg (Addl. 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	08.11.08

		lower Total-C and LDL-C to target levels.	
237	Paclitaxel inj.30/100/300mg vial (Addl. Indication)	For the treatment of advanced gastric carcinoma	08.11.08
238	Montelukast + Desloratidine(10mg + 5mg) FC Tablets	For the treatment of allergic rhinitis in adults only	10.11.08
239	Amlodipine + Metoprolol (2.5/5 mg + 25/50mg (ER))Tablets	Additional Lower Strength	10.11.08
240	Losartan + HCTZ (100 mg + 25 mg) Tablets	Additional Strength	10.11.08
241	Phenylramidol HCl tablet 400mg	For the treatment of lumbago, integumental pain, musculoskeletal pain	14.11.08
242	Salicylic Acid + Coal Tar (3% + 1%) Solution	For scaling of seborrhea, seborrheic dermatitis, psoriasis of scalp	17.11.08
243	Salicylic Acid + Coal Tar + Precipitated Sulphur (3% + 1% + 3%) Ointment	For the treatment of psoriasis and fungal skin infection	17.11.08
244	Thiocolchicoside + Etoricoxib(4mg + 60 mg) FC Tablets	For the acute treatment of inflammatory musculoskeletal disorders associated with painful muscle spasm in adults.	17.11.08
245	Tamsulosin + Tolterodine (0.4mg MR Pellets + 2mg/4mg ER Pellets) Capsules	Additional Lower Strength	17.11.08
246	Calcium Hypochlorite 4gm Sachet (Calcium Hypochlorite 0.542% Other Ingredients: 99.458%)	For purification of contaminated ground water sources.	23.11.08
247	Sumatriptan + Naproxen (50mg + 275mg) Tablets	Additional Lower Strength	24.11.08

248	Amoxicillin + Clavulanic acid(1gm + 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	25.11.08
249	Buprenorphine + Naloxone (2 mg/0.4mg + 0.5/0.1 mg) Tablets	Additional Lower Strength	02.12.08
250	Atorvastatin + Metformin(10mg + 500mg SR) Tablets	As adjunctive therapy to diet and exercise in patients with diabetic dyslipidemia	04.12.08
251	Pemetrexed disodium 500mg / 100mg powder for sol. (Addl. 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	04.12.08
252	Magnesium Valproate Tablet 200mg/400mg	For the treatment of generalized or partial seizures as monotherapy or adjunctive therapy. For the treatment of manic episodes associated with bipolar disorders. For prophylaxis of migraine headache in adults.	04.12.08
253	Ursodeoxycholic Acid 300/600 SR Tablets (Additional Strength)	For the dissolution of Radiolucent colic stones, chronic cholestatic liver disease in particular primary biliary cirrhosis, primary sclerosing cholangitis & cholestasis associated with cystic fibrosis.	08.12.08
254	Rifampicin + INH + Piperine (200mg + 300mg + 10mg ) Capsules	For the treatment of adult patients with pulmonary tuberculosis	11.12.08

255	Rifampicin +Piperine (200mg + 10mg ) Capsules	For the treatment of adult patients with pulmonary tuberculosis	11.12.08
256	Amphotericin B Lipid suspension 50mg/ vial (Addl. Strength)	Additional Strength	12.12.08
257	Desmopressin Acetate tablet 0.1/0.2 mg	For the treatment of cranial diabetes insipidus , primary nocturnal enuresis in patients.	12.12.08
258	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	16.12.08
259	Lamotrigine MR Tablets 50/100mg	For the treatment of bipolar I disorder. (addl. Indication)	17.12.08
260	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.	17.12.08
261	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.	17.12.08
262	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.	17.12.08

263	Salicylic Acid + Cetyl Alcohol + Stearyl Alcohol (2% + 2.65% + 0.26%) Lotion	For the treatment of scaly dermatoses	18.12.08
264	Azathioprine 25mg Tablets	Additional Strength	19.12.08
265	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	23.12.08
266	Gemifloxacin + Ambroxol (320mg + 75mg SR) FC Tablets	Indicated for the treatment of lower respiratory tract infections in adult patients	24.12.08
267	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	24.12.08
268	Paracetamol + Phenylephrine Hydrochloride (Each 6gm Sachet contains: 500mg + 10mg) Sachet	For the treatment of fever associated with cold, nasal congestion in adults	24.12.08
269	Carboinoxamine Maleate + Ammonium Chloride + Sodium Citrate (Each 5 ml contains: 2 mg + 120 mg + 120 mg) syrup	For symptomatic treatment of cough	24.12.08
270	Diclofenac + Thiocolchicoside (50 mg + 4 mg) Capsules	Additional Lower Strength	24.12.08