

LIST OF NEW DRUGS APPROVED IN INDIA FROM 1991 TO 2000

S. No	Name of Drug	Pharmacological action/ Indication	Date of Approval
1	Ciprofloxacin 0.3% w/v Eye Drops/Eye Ointment/Ear Drop	Indicated in the treatment of external ocular infection of the eye.	February-1991
2	Diclofenac Sodium 1gm Gel		March-1991
3	i)Cefaclor Monohydrate 250mg/500mg Capsule. ii)Cefaclor Monohydrate 125mg/5ml & 250mg/5ml Suspension. iii)Cefaclor Monohydrate 100mg/ml Drops. iv)Cefaclor 187mg/5ml Suspension (For paediatric use).	Antibiotic- In respiratory infections, ENT infection, UT infections, Skin and skin structure infections.	April-1991
4	Sheep Pox Vaccine (For Veterinary)		April-1991
5	Omeprazole 10mg/20mg Enteric Coated Granules Capsule	Short term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, management of Zollinger-Ellison syndrome.	April-1991
6	i)Nefopam Hydrochloride 30mg Tablet. ii)Nefopam Hydrochloride 20mg/ml Injection.	Non narcotic analgesic- Acute and chronic pain, including post-operative pain, dental pain, musculo-skeletal pain, acute traumatic pain and cancer pain.	April-1991
7	Buparvaquone 5% w/v Solution for Injection (For	Indicated in the treatment of bovine theileriosis.	April-1991

	Veterinary)		
8	i)Kitotifen Fumerate 1mg Tablet ii)Kitotifen Fumerate Syrup iii)Ketotifen Fumerate Nasal Drops	Anti asthmatic drug- Indicated in prophylactic treatment of bronchial asthma, symptomatic improvement of allergic conditions including rhinitis and conjunctivitis.	May-1991
9	i)Pefloxacin Mesylate Dihydrate 400mg Film Coated Tablet ii)Pefloxacin Mesylate Dihydrate 400mg/5ml Injection iii)Pefloxacin Mesylate Dihydrate 400mg I.V Bottles of 100ml/200ml	Antibacterial- In the treatment of severe infection in adults caused by sensitive microorganism (gram -ve pathogens and staphylococci).	May-1991
10	Ofloxacin 100mg/50ml & 200mg/100ml vial Infusion	Indicated in RTI, UTI, gynaecological infection, skin/soft lesion infection.	May-1991
11	Nitrendipine 10mg/20mg Tablet	Anti hypertensive- In the treatment of mild to moderate hypertension.	May-1991
12	Isosorbide-5-Mononitrate 25mg/50mg/40mg SR Tablet	Indicated in prophylaxis of angina pectoris, CHD post MI, therapy pulmonary hypertension.	May-1991
13	Roxatidine Acetate Hcl 75mg SR Tablet	Anti ulcer- Disorders in the upper gastric intestinal region i.e duodenal ulcer, benign gastric ulcers.	May-1991
14	Felodipine 5mg/10mg ER Film Coated Tablet	Anti hypertensive- In the treatment of hypertension.	May-1991
15	Rabbit Anti Human Thymocyte Immunoglobulin		May-1991

16	Pirarubicin Hcl Injection	Anti Cancer.	May-1991
17	Horse Anti Human Lymphocyte Globulin	For aplastic anaemia.	May-1991
18	Ramipril 1.25mg/2.5mg/5mg/10mg Capsule	ACE inhibitor- Indicated in the treatment of hypertension, cardiac failure. And also for myocardial infarction.	August-1991
19	Selegiline Hcl 5mg Uncoated Tablet	Parkinsonism- Indicated in the treatment of Parkinson's disease.	August-1991
20	Piroxicam USP 20mg/ml (i.m) Injection	Indicated in the treatment of musculoskeletal disorders, acute gout, pain after operative intervention following acute trauma and in primary dysmenorrhoea (12 years age or older).	August-1991
21	Perindopril 2mg/4mg Tablet	Anti hypertensive- Indicated in the treatment of hypertension.	September-1991
22	Ethamsylate 250mg/2ml ampoule Injection	Indicated in the Treatment of small vessel haemorrhage, menorrhagia, prophylaxis of periventricular haemorrhage in neonates.	September-1991
23	Mupirocin 2% w/w Topical Ointment	For bacterial skin infection.	September-1991
24	Nilutamide Tablets	Indicated in the treatment of metastatic or localised cancer of the prostate.	October-1991
25	Lisinopril Dihydrate 10mg/20mg/2.5mg/5mg Tablet	Essential hypertension and in patients with congestive heart failure.	November-1991
26	Ofloxacin 3mg/ml Eye Drops	In tropical treatment of	December-1991

		external infections of the eye and its adnexa caused by susceptible bacteria.	
27	Clomipramine Hcl 10mg/25mg/50mg Tablet	Anti depressant- Obsessive compulsive disorders, phobic states and depression (when sedation is required).	February-1992
28	Clomipramine Hcl 50mg Capsule	Anti depressant- Obsessive compulsive disorders, phobic states and depression (when sedation is required).	February-1992
29	Bisoprolol Fumerate (2:1) 5mg/10mg Film Coated Tablet	Anti hypertensive- Hypertension, coronary heart disease (angina pectoris).	27-2-1992
30	Amsacrine Injection	Anti cancer.	26-2-1992
31	Fusidic Acid BP 10mg/gm Eye Drops		3-3-1992
32	Fusidic Acid Hemihydrate Eye Drops	Bacterial infection of the eye caused by susceptible organism in conjunctivitis, blepharitis, stykeratitis, dacryocystitis. It can be used for prophylaxis in ophthalmic surgery and in connection with removal of foreign bodies.	March-1992
33	i)Roxithromycin 150mg/300mg Film Coated Tablet ii)Roxithromycin 50mg Kid Tablet iii)Roxithromycin 50mg Dispersible Tablet iv)Roxithromycin 50mg/5ml	Antibiotic- Sensitive strain infections of ENT, bronchopulmonary tract infection, genital except for gonococcal infections, prophylaxis of meningococcal meningitis in exposed subjects.	27-3-1992

	Dry Syrup		
34	Sodium Enoxaparin Low Molecular Weight Heparin 20mg/40mg Injection	As a prophylactic in the treatment of thromboembolic disorders during orthopaedic surgery, general surgery and haemodialysis.	13-3-1992
35	Metoclopramide Hcl IP 15mg C.R Tablet	To restore normal coordination and tone the upper digestive tract and relieve symptoms of gastro-duodenal dysfunction including heart burn, dyspepsia, nausea and vomiting associated with such conditions as reflux oesophagitis, gastritis, duodenitis and hiatus hernia.	13-4-1992
36	Ketorolac Tromethamine 10mg Film Coated Tablet	Non steroidal analgesic anti inflammatory- Indicated in the treatment of short term management of post operative pain and musculo-skeletal pain.	21-4-1992
37	Ketorolac Tromethamine 30mg/ml & 15mg/ml (i.m) Injection	Non steroidal analgesic anti inflammatory- Indicated in the treatment of short term management of post operative pain and musculo-skeletal pain.	21-4-1992
38	Ipratropium Bromide 250mcg/ml Respirator Solution		8-4-1993
39	Ipratropium Bromide 20mcg Nasal Spray		8-4-1993
40	Betaxolol Hcl 0.5% w/v per 5ml Ophthalmic Solution	Ocular hypertension and chronic open angle glaucoma.	1-5-1992
41	Gadopentetic Acid	Contrast media- Cranial and	6-5-1992

	Dimeglumine Salt 469.01mg/ml Injection	spinal magnetic resonance tomography.	
42	Pyridoxine Hcl 100mg C.R Tablet	Deficiency of vit.B6 caused by usage of oral contraceptive pill/drug induced pyridoxine deficiency.	7-5-1992
43	Cephacetrile Sodium 235mg in 10gm of suspension Intramammary Infusion (For Veterinary)	Mastitis caused by streptococcus agalactial, str. dysgalactial, str. Uberis, str. Aureus (both penicillin-sensitive and resistant strain) gram negative bacterial including E. coli and klebsiella.	13-5-1992
44	Feracrylum 1% w/v Solution	External haemostatic agent.	21-5-1992
45	Oral Polio Vaccine	Vaccine (polio) oral.	6-5-1992
46	Korsolex Concentrated Instrument Disinfectant	Disinfectant instrument.	20-5-1992
47	Sterillium Rub in Disinfectant for Hands.	Disinfectant for hands.	20-5-1992
48	Bacillocid Special	Disinfectant surface.	20-5-1992
49	Loratidine 10mg Tablet	Long acting anti histaminic- In treatment of allergic rhinitis, acute coryza, chronic idiopathic urticaria.	19-6-1992
50	Dexfenfluramine Hcl 15mg Capsule	Anti obesity drug- Indicated in association with diet in the treatment of uncomplicated obesity, complicated obesity in adults, of refractory obesity, and of obesity involving disorders of dietary behaviour (carbohydrate compulsion).	22-6-1992
51	Bacillus Calmette and Geurin	Anti cancer- To be indicated	22-6-1992

	(Immucyst, BCG therapeutics) 27mg dry weight per Vaccine	for intravesical use in the treatment of primary and relapse carcinoma in-situ of the urinary bladder.	
52	Candur P. Parvovirus Vaccine (For Veterinary)	Indicated in active immunization of dogs against parvovirus infection.	9-7-1992
53	Naloxone Hcl 0.02mg/0.4mg/1.0mg per ml (i.v/i.m/s.c) Injection	Indicated for the complete partial reversal of narcotic depression including respiratory depression, induced by opioids including natural and synthetic narcotics, propoxyphene methadone, and certain narcotic-antagonist analgesics, nalbuphine, pentazocin and butorphenol.	28-7-1992
54	i)Nimodipine 30mg Tablet ii)Nimodipine 10mg/50ml Injection iii)Nimodipine 30mg Soft Gelatin Capsule	In the treatment and prevention of ischaemic neurological deficit occurring due to arterial spasm, following sub arachnoid haemorrhage.	31-8-1992
55	Ginko Biloba 40mg Film Coated Tablet	Herbal extract- In treatment of disorders in the functioning of the brain (reduced intellectual ability and alertness), giddiness buzzing in the ears, headache, poor memory, weakening of the voice resulting from anxiety.	8-9-1992
56	Hamycin 0.1% per gm Hair Cream		September-1992
57	Clindamycin Phosphate 1% per	Indicated in treatment of acne	October-1992

	gm Topical Gel	vulgaris.	
58	Itrolan 190 (0.406g/ml), Itrolan 240 (0.513g/ml), Itrolan 300 (0.641g/ml) Injection	Contrast media.	23-10-1992
59	Pipecuronium Bromide 4mg per vial Injection	Non depolarising muscle relaxing agent- In the treatment of as an adjunct to general anaesthesia to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgical procedure of medium and large duration.	3-11-1992
60	Cisapride 5mg/10mg/20mg Tablet & Cisapride 1mg/ml Suspension.	Gastro intestinal disorders- Oesophagitis and gastro oesophageal reflux disorders, chronic functional and non ulcer dyspepsia, gastroparesis intestinal pseudo obstruction and constipation.	6-11-1992
61	Tetrachlorodecaoxide 1.037mg/100ml Solution	Immuno modulator (tissue repair) of wounds with impaired healing such as infected wound, delayed post traumatic and post operative wound healing and delayed healing after operation.	6-11-1992
62	Ipratropium Bromide 20 mcg Inhaler	Anti cholinergic bronchodilator- Chronic obstructive bronchitis, emphysema, bronchospasm, during and after surgery and moderate to asthmatic attacks	20-11-1992

		in chronic form of asthma.	
63	Banoxinate Hcl Ophthalmic Solution	Indicated for use as an anaesthesia of cornea and conjunctivitis for ophthalmic procedure.	24-11-1992
64	i)Tramadol Hcl 50mg/100mg Capsule ii)Tramadol Hcl 50mg/ml & 100mg/2ml Injection	Analgesic- Severe acute and chronic pain, diagnostic measures and surgical pain.	27-1-1993
65	i)Fluconazole 50mg/100mg/200mg Capsule ii)Fluconazole 2mg/ml 100ml/200ml i.v Injection	For the treatment of systemic candidiasis, mucosal candidiasis, cryptococosis, prevention of fungal infections in patients with malignancy.	28-1-1993
66	Ticlopidine Hcl 250mg Tablet	Antiplatelet agent- for the prevention of cerebro and cardio vascular accidents in patients suffering from arterial insufficiency in the legs and cerebral vessels and correction of platelet disorders induced by extra corporeal circuits during surgery with extra corporeal circulation or haemodialysis (artificial kidney).	11-2-1993
67	Purified Vi-Capsular Polysaccharide of Salmonella Typhi 0.025mg + Phenol 1.250mg + Isotonic Buffer Solution q.s 0.5ml (One vaccinating dose of 0.5ml)	Vaccine against typhoid fever.	12-2-1993
68	Cefixime 100mg/200mg/400mg	Oral cephalosporin- in the treatment of UTI, respiratory	24-2-1993

	Capsule/Tablet	tract infections, billiary tract infections.	
69	i)Flecainide Acetate 100mg Tablet ii)Flecainide Acetate 150mg/ml (15ml) Injection	Antiarrhythmic.	26-3-1993
70	Bezafibrate 400mg Film Coated Retard Tablet		2-4-1993
71	i)Fluconazole 50mg/100mg/150mg/200mg Capsule/Tablet ii)Fluconazole 2mg/ml i.v Injection		26-4-1993
72	Tenoxicam 20mg Tablet	NSAID- rheumatoid arthritis, osteoarthritis, arthrosis, ankylosing spondylitis, gout, non-articular rheumatic conditions.	29-4-1993
73	i)Secnidazole 500mg Tablet ii)Secnidazole 1gm Film Coated Tablet iii)Secnidazole 500mg/15ml Suspension	Intestinal amoebiasis, amoebic hepatitis, trichomonal vaginitis, bacterial vaginitis and giardiasis.	13-5-1993
74	Carbamezepine 200mg/400mg C.R Film Coated Tablet		17-5-1993
75	Oral Typhoid Vaccine Caps	Prophylaxis of Typhoid.	17-5-1993
76	Amlodipine Besylate 5mg/10mg/2.5mg Tablet	Indicated in hypertension, angina pectoris.	19-5-1993
77	Paspal Injection	Bronchial asthma, spastic bronchitis, allergic rhinitis, summer conjunctivitis, allergic dermatosis.	27-5-1993
78	Mepatricin 50000 Units	Functional disorders in benign	28-5-1993

	Enteric Coated Tablet	prostatic hypertrophy.	
79	Nitroglycerin 25mg/50mg Patch	For the treatment of angina pectoris due to coronary artery disease.	3-6-1993
80	i)Cetirizine Dihydrochloride 20mg/10mg/5mg Film Coated Tablet ii)Cetirizine DHC 10mg/10ml Syrup iii)Cetirizine DHC 10mg/ml Drops	Seasonal rhinitis and conjunctivitis, perannual allergic rhinitis, pruritis and urticaria.	25-6-1993
81	Cumophos 50% (For Veterinary)		5-7-1993
82	Triptorelin Controlled Release Injection	For the treatment of prostate cancer, ovarian cancer, breast cancer, precocious buperty, uterine fibroids, myomes, polycystic ovarian disease and pre-treatment in I.V.F.	5-7-1993
83	i)Maduramicin Amonium 10gm ii)Maduramicin Amonium 0.5% (1% Premix) (For Veterinary)	As an acid for the prevention of coccidiosis in broiler chickens.	7-7-1993
84	Fenfluramine Hcl 60mg S.R Capsule		9-7-1993
85	Diclofenac Sodium 25mg/ml Injection (For Veterinary)		14-7-1993
86	Metronidazole 1% w/w (Skin Ointment) Gel		19-7-1993
87	Itraconazole 100mg Capsule	Systemic aspergillosis and candidas cryptococcosis, sporotrichosis,	20-7-1993

		paracoccidioidomycosis, blastomycosis and other rarely occurring systemic or tropical mycoses.	
88	Chelated Amino Acid based minerals	Trace mineral deficiencies.	20-7-1993
89	Zalcitabine 0.375mg/0.750mg Film Coated Tablet	For the treatment of AIDS.	26-7-1993
90	Candur-R (Purified Chick Emryo Cell Rabies Vaccine) (For Veterinary)		13-8-1993
91	Cefoperazone Sodium 1g/2g per vial Injection		23-8-1993
92	Calcitriol 0.5mcg/0.25mcg Soft Gelatin Capsule	For the treatment of metabolic bone disease.	27-8-1993
93	Glucomannan 0.75gm/1.0gm/1.3gm Sachet	For reduction of blood glucose level reduction serum lipid level.	6-9-1993
94	Aspirin 325mg/500mg Delayed Release Tablet		6-9-1993
95	Calcium loaded sulfonated polystyrene cation exchange resin 0.5gm (eq. to 1.8mEq Ca ⁺⁺) cross linked with 8% divinyl benzene Soft Gelatin Capsule		13-9-1993
96	Piribedil 50mg S.R Coated Tablet	Of impaired attentiveness and/or memory or feelings of giddiness in elderly, pain full symptoms of arterial disease, idiopathic Parkinson's disease.	27-9-1993
97	Diclofenac Sodium 50mg Dispersible Tablet		30-9-1993

98	Filgrastim 48MU (1.6ml) & Filgrastim 30MU (1ml) Injection		30-9-1993
99	Dobutamine Hcl 50mg/ml (Infusion Concentrate) Injection	Indicated when parenteral therapy is necessary for inotropic support in the short term treatment of cardiac decompensation due to depressed contractility resulting either from organic heart disease or from cardiac surgical procedures.	4-10-1993
100	Sulphachloropyrazine Sodium 30% (For Veterinary)		18-10-1993
101	Nicardipine Hcl 20mg/30mg Capsule	In treatment of hypertension and chronic stable angina pectoris.	27-10-1993
102	Pefloxacin Mesylate Dihydrate 0.3% w/v Eye Drops		12-11-1993
103	Depo-Provera Injection		18-11-1993
104	Flunisolide 0.025% w/v Nasal Spray	For the prophylaxis and treatment of perennial and seasonal allergic rhinitis including hay fever.	30-11-1993
105	Colfosceril Palmitate 108mg per vial Injection	New born babies with birth weight of 700gm or greater, undergoing mechanical ventilation of respiratory distress syndrome, whose heart rate and arterial oxygenation are continuously monitored.	1-12-1993
106	i)Salmeterol Xinafoate 25mcg Inhaler	Long term regular treatment of reversible airway obstruction	1-12-1993

	ii)Salmeterol Xinafoate 50mcg Rotacap	in asthma, and chronic bronchitis.	
107	Tizanidine Hcl 2mg/4mg Tablet	Painful muscle spasm, spasticity due to neurological disorders.	22-12-1993
108	Ioversol 160/240/300/320/350 Injection	Contrast media.	29-12-1993
109	i)Enrofloxacin 100mg/50mg per ml Injection ii)Enrofloxacin 50mg/100mg per ml Oral Solution (For Veterinary)		10-1-1994
110	Clostridium Botulinum Toxin Type A Hemagglutinin Complex 100 units. Human Serum Albumin 0.5mg + NaCl 0.9mg per vial (i.m) Injection	For the treatment of blepharospasm hemifacial spasm associated focal dystonias.	13-1-1994
111	Gadodiamide 287mg/ml Injection eq. to 0.5 m mol (in 10ml vial)	Contrast media.	21-1-1994
112	i)Ondansetron Hcl Dihydrate 4mg/8mg Film Coated Tablet ii)Ondansetron Hcl Dihydrate 4mg/2ml ampoule Injection iii)Ondansetron Hcl Dihydrate 8mg/4ml ampoule Injection	In the treatment and management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.	12-2-1994
113	Estraderm Transdermal TTS having Estraderm 2mg/4mg/8mg Estradiol.		23-2-1994
114	Chandonium Iodide 2mg/ml 2ml ampoule Injection	Marketed as neuromuscular blocking agent.	1-3-1994
115	Diclofenac Potassium 50mg Sugar Coated Tablet		18-3-1994

116	Calcitriol 1mcg/2mcg per ml Injection		19-3-1994
117	i)Vancomycin Hcl 500mg/1000mg per vial Injection ii)Vancomycin Hcl 125mg/250mg Capsule		28-3-1994
118	Dihydrotestosterone Gel		25-4-1994
119	Collagenase 250 units per gm Ointment	In the treatment for debriding chronic dermal and severely burn areas.	5-5-1994
120	i)Azithromycin Dihydrate 250mg Capsule ii)Azithromycin 200mg/50mg per 5ml Suspension	For susceptible infections including community acquired pneumonia pelvic inflammatory disease.	13-5-1994
121	Diltiazem Hcl 5mg/ml Injection		16-5-1994
122	Lomefloxacin 400mg Tablet	In the treatment of mild to moderate infections caused by susceptible strains of designated micro-organism in RTI uncomplicated and complicated UTI.	20-5-1994
123	Octreotide Injection		30-6-1994
124	Morphine Sulphate 60mg Film Coated CR Tablet		18-7-1994
125	i)Terconazole 80mg Vaginal Ovule ii)Terconazole 0.8% Vaginal Cream	For the local treatment of vulvovaginal candidiasis (moniliasis).	19-7-1994
126	Paclitaxel 30mg/5ml single dose vial Injection	Advanced epithelial carcinoma of the ovary after failure of first line or subsequent	25-8-1994

		chemotherapy.	
127	i)Esmolol Hcl 2.5gm/10ml ampoule Injection ii)Esmolol Hcl 100mg/10ml vial Injection	Supraventricular tachycardia for rapid control of ventricular rates patients with atrial fibrillation or artrial flutter in perioperative, post-operative circumstances where short term control of ventricular rate is desirable.	29-8-1994
128	Naproxen 10% w/w Topical Gel		31-8-1994
129	Genotropin 4iu/12iu/16iu Injection	Short stature due to inadequate or failed incretion of pituitary growth hormone.	5-9-1994
130	Omeprazole Sodium 40mg per vial Injection		6-9-1994
131	Closantel 15% Oral Solution (For Veterinary)	Mature and immature fasciola species, haemonchus species, strongyloides species, and also for external parasites like oestrus ovis boophilus microplus hyalomma a anatolicum in cattle and sheep.	3-10-1994
132	Medicated Pad with Cetylpyridinium Chloride 0.3% w/w each perforated fresh coloured Self Adhesive Plaster Strip		6-10-1994
133	Clomipramine Hcl 75mg SR Tablet		19-10-1994
134	Celiprolol Hydrochloride 100mg/200mg/400mg Film Coated Tablet	Mild to moderate hypertension, angina pectoris.	1-12-1994

135	1,2-Dimethyl-3 Hydroxypyrid-4-one 250mg/500mg Capsule		7-12-1994
136	Haemophilus Type-b Conjugate Vaccine	For the indication in infants from 2 months for the prevention of invasive disease such as meningitis, septicemia epiglottitis.	13-12-1994
137	Lansoprazole 15mg/30mg (as enteric coated granule) Capsule	For the treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, Zollinger-Ellison syndrome.	16-12-1994
138	i)Nimesulide 100mg Tablet ii)Nimesulide 50mg/5ml Suspension iii)Nimesulide Transdermal 1% Gel iv)Nimesulide 50mg/100mg Suppository	Inflammatory condition including joint disorders such as rheumatoid arthritis, post traumatic and post operative painful condition and fever.	13-1-1995
139	Clonazepam 0.5mg/1.0mg/2.0mg Tablet	In the treatment of petitmal and its variant, akinetic and myoclonic seizures.	25-1-1995
140	Diclofenac Sodium 0.1% (1mg/ml) Ophthalmic Solution Sterile	Indicated in post operative inflammation in patients who have undergone cataract operation.	27-1-1995
141	Terazosin Hcl 1mg/2mg/5mg Tablet	In the treatment of essential hypertension and BPH.	27-1-1995
142	Cefaclor 375mg/750mg MR Tablet		27-1-1995
143	Fortison Liquid/Powder, Pepti-2000 Liquid/Powder		27-1-1995
144	i)Ritodrine Hcl 10mg Tablet ii)Ritodrine Hcl USP 10mg/ml	Premature labours, acute foetal distress, prevention of preterm	21-2-1995

	Injection	labours after operations.	
145	Rilmenidine Dihydrogen Phosphate 1mg Tablet	Mild to moderate hypertension.	21-2-1995
146	Disodium Pamidronate Injection	Tumour inducer hypercalcaemia.	21-2-1995
147	Tromantadine Hcl 1gm Ointment	Herpes simplex infection of the skin.	23-2-1995
148	Permethrin 5% Cream	Infestation with sarcopyto scabies.	6-3-1995
149	Formestane Sterile 250mg (i.m) Depot Injection	For the treatment of advance stage of breast cancer in women with natural or artificially induced post menopausal status.	6-3-1995
150	Clozapine 25mg/100mg Uncoated Tablet	Indicated in the management of schizophrenic patients.	7-3-1995
151	Etidronate Disodium 200mg Tablet	Hypercalcemia induced by various malignant disorders.	10-3-1995
152	Altretamine 50mg Capsule	For palliative treatment of patients with persistent or recurrent ovarian cancer, following first line therapy with cisplatin and/or alkylating agent based combination.	10-3-1995
153	i) Clarithromycin 250mg/500mg Tablet ii) Clarithromycin 125mg/250mg per ml Paediatric Suspension	Of mild to moderately severe infections like acute exacerbation of chronic bronchitis community acquired pneumonia including infections due to chlamydia, mycoplasma spegiocella acute streptococcal pharyngitis and skin and soft tissue infections.	22-3-1995

154	Terbinafine 250mg Tablet Terbinafine 1% Cream	Fungal infection of skin, hair nails.	29-3-1995
155	Somatostatin i.v Infusion	Severe acute haemorrhage from oesophageal varices/gastric or duodenal ulcers or acute erosive or haemorrhagic gastritis adjuvant treatment in pancreatic biliary and intestinal fistulae. Prophylaxis and treatment of postoperative complication following pancreatic surgery, adjuvant treat in diabetic keratoacidosis.	24-4-1995
156	Podophyllotoxin 0.5% each 3-5ml Topical Solution	Anogenital warts, non genital warts only.	5-5-1995
157	Nicotine Transdermal Therapeutic System		17-5-1995
158	Tenoxicam 20mg Dispersible Tablet		31-5-1995
159	Progesterone Micronized Soft Gelatin Capsule		21-6-1995
160	Prazosin Hcl (GITS) Tablets		21-6-1995
161	Silymarin 70mg/140mg Sugar Coated Tablet	For supportive treatment in chronic liver disease and cirrhosis.	22-6-1995
162	Naproxen 750mg C.R Tablet		26-6-1995
163	Coumarin Tablet		July-1995
164	Terlipressin Acetate 1mg per vial Injection	In the treatment of bleeding oesophageal varices.	22-7-1995
165	i) Salmon Calcitonin 100 IU/ml each ampoule Injection ii) Salmon Calcitonin 400	Hypercalcaemia pain associated with advanced metastatic bone cancer, Paget's	3-8-1995

	IU/2ml each vial Injection	disease, post menopausal osteoporesis.	
166	Gabapentin 300mg/400mg Capsule	Epilepsy.	3-8-1995
167	Danofloxacin Mesylate 25mg per ml Injection (For Veterinary)	Bovine respiratory disease in beef cattle; non lactating dairy cattle calves caused by pasteurella haemolytica, p. Multocida & enteric infection caused by E. coli/salmonella.	12-8-1995
168	Baclofen USP 10mg/25mg Tablet		29-9-1995
169	Lovastatin 10mg/20mg/40mg Tablet	Reduction of total LDL cholestrol in patients of primary hypercholesterolemia (type-IIa & IIb hyperlipoproteinemia).	5-10-1995
170	i)Ambroxol Hcl 30mg ii)Ambroxol Hcl 30mg/5ml Liquid iii)Ambroxol Hcl 7.5mg/ml Drops	Antitussive- acute and chronic disease of the respiratory tract associated with abnormal bronchial secretions in particular acute attacks of chronic bronchitis, asthmatic bronchitis, bronchial asthma.	1-12-1995
171	Gemcitabine Hcl 200mg/1000mg Injection	In the management of non small cell lung cancer.	24-1-1996
172	i)Sumatriptan (as Succinate) 100mg/50mg/25mg Film Coated Tablet ii)Sumatriptan as Succinate 6mg/0.5ml Injection	Acute migraine attacks with or without aura, only where there is a clear diagnosis.	6-2-1996
173	Tacrine Hcl 10mg/20mg/30mg/40mg	For the treatment of dementia in patients with Alzheimer's	14-2-1996

	Capsule	disease of mild to moderate severity.	
174	Nitroscanate 100mg/500mg Tablet (For Veterinary)	For control/eradication of hook worms/round worms/tape worms in puppies and adult dogs.	19-2-1996
175	Ketorolac Tromethamine 0.5% Sterile Ophthalmic Solution	For the relief of ocular itching due to seasonal allergic conjunctivitis only.	1-3-1996
176	i)Cefpodoxime Proxetil 100mg Tablet ii)Cefpodoxime Proxetil 40mg/5ml Dry Syrup		12-3-1996
177	i)Fluticasone Propionate 0.05% Cream ii)Fluticasone Propionate 0.005% Ointment iii)Fluticasone Propionate 0.05% Nasal Spray	Inflammatory and pruritic manifestation of corticosteroid responsive eczema dermatitis.	18-3-1996
178	Amifostine 500mg per vial Sterile Lyophilised Powder For Injection	Indicated as a chemoprotective agent against the serious toxicities associated with intensive regimens of platinum and alkylating agent chemotherapy (on reconstitution each ml will contains 50mg amifostine).	21-3-1996
179	Piroxicam Betacyclodextrin 20mg Tablet	Pain and inflammation associated with rheumatoid arthritis, osteoarthritis, acute musculo-skeletal pain, tendinitis, bursitis, post traumatic disorders, post	25-3-1996

		operative pain, primary dysmenorrhoea.	
180	Thiocolchicoside 4mg Tablet	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.	25-3-1996
181	Fusafungine	Old drug with new pump system.	26-3-1996
182	Sulbutiamine 200mg Sugar Coated Tablet	Symptomatic treatment of functional asthenia.	22-4-1196
183	Benazepril Hcl 5mg/10mg/20mg Tablet	Essential hypertension and congestive heart failure.	22-4-1996
184	Goserelin acetate 3.6mg Injection	In the treatment of prostate cancer, breast cancer, endometriosis.	24-4-1996
185	Levobunolol Hcl USP 2.5mg/5.0mg per ml Ophthalmic Solution	For the control of intra-ocular pressure in chronic open angle glaucoma and ocular hypertension.	16-5-1996
186	Dipivefrin Hcl USP 0.1% Ophthalmic Solution	For the control of intra-ocular pressure in chronic open angle glaucoma.	16-5-1996
187	N-butyl Cyanoacrylate 0.5ml Bioadhesive (Liquid adhesive)	For treatment of smooth and fresh skin wounds and surgical incision.	6-6-1996
188	Indapamide 1.5mg SR Coated Tablet		12-6-1996
189	Rocuronium Bromide 50mg/5ml & 100mg/10ml	As an adjuvant to general anaesthesia to facilitate	18-6-1996

	Injection	endotracheal incubation to provide skeletal muscle relaxation during surgery.	
190	Beriplast (Fibrin Adhesive Glue)	Tissue adhesion, suture support, haemostasis, wound care, sealing of body cavities and subarachnoid space only.	19-6-1996
191	Docetaxel Trihydrate 80mg (2ml/vial) and 20mg (0.5ml/vial) with docetaxel solvent 6ml & 1.5ml Injection	Indicated in the treatment of patients with locally advanced or metastatic breast cancer and small cell lung cancer.	20-6-1996
192	Carteolol Hcl 5mg Film Coated Tablet	In the management of hypertension and also in the prophylactic management of patients with angina pectoris.	9-7-1996
193	Carteolol Hcl 2% w/v Sterile Ophthalmic Solution	Ophthalmic solution is indicated in ocular hypertension, chronic open angle glaucoma and some secondary glaucoma's.	9-7-1996
194	Sevoflurane Inhalation	For induction and maintenance of general anaesthesia in all procedures and patients types.	9-7-1996
195	Polysachharide Pneumococcal Vaccine (Pneumo 23)	Marketed for the prevention of pneumococcal pneumonia and pneumococcal systemic infections caused by the serotypes included in the vaccine.	9-7-1996
196	i)Fluorometholone 0.1% Ophthalmic Suspension ii)Fluorometholone Forte 0.25% Liquifilm Suspension	In non infected/infected inflammatory ocular condition.	26-7-1996

197	i)Artemether 80mg per ampoule Injection ii)Artemether 40mg Capsule	Promoted for use in severe malaria including cerebral malaria and as a second line in chloroquine resistant malaria cases only.	2-8-1996
198	Amitraz BP 50mg/125mg per ml Emulsifiable Concentrate (For Veterinary)		6-8-1996
199	Benidipine Hcl 4mg/8mg Film Coated Tablet	Hypertension and long term prophylactic management of angina pectoris.	12-8-1996
200	Influenza Vaccine Inactivated (Vaxigrip)	Prophylaxis against influenza.	13-8-1996
201	Centpropazine 20mg Capsule	In the treatment of depression.	16-8-1996
202	Zopiclone BP 7.5mg Tablet	Short term treatment of insomnia, transient, situational or chronic insomnia and insomnia secondary to psychiatric disorders where it is desilitating or severe.	16-8-1996
203	Glipizide 5mg/10mg GITs Tablet	Non insulin dependent diabetes mellitus (NIDDM type-II)	21-8-1996
204	Fish Gut Sutures		28-8-1996
205	Paracetamol 650mg SR Tablet		August-1996
206	Artesunate 60mg per ampoule Injection	Promoted for use in severe malaria including cerebral malaria and as a second line in chloroquine resistant malaria cases only.	2-9-1996
207	Cypermethrin High Cis 100gm per litre (For Veterinary)	For the control of tick, flies, lice and mites on cattle, sheep, dogs and poultry.	16-9-1996
208	Promegestone	Gynaecological conditions	23-9-1996

	0.125mg/0.250mg/0.500mg Tablet	characterized by luteal insufficiency, menstrual irregularities due to ovulation disorders, dysmenorrhea, premenstrual syndrome, mastodynia, dysfunctional uterine bleeding menorrhagia due to fibromyomas, menopausal syndrome.	
209	Artesunate 50mg Tablet		7-10-1996
210	Nicardipine Hcl 40mg/30mg (as pellets) Retard Capsule	Management of hypertension and angina pectoris.	9-10-1996
211	Finasteride 5mg Film Coated Tablet	Benign prostatic hypertrophy only.	9-10-1996
212	Naltrexone Hcl 50mg Uncoated Tablet	In the treatment of narcotic antagonist and alcohol dependence.	11-10-1996
213	Tibolone 2.5mg Tablet	In the treatment of complaints resulting from the natural or surgical menopause.	16-10-1996
214	Amoxicillin Trihydrate 750mg Bolus (For Veterinary)		16-10-1996
215	Sparfloxacin 100mg/200mg/400mg Tablet	Community acquired pneumonia, acute exacerbation of chronic bronchitis, other lower respiratory tract infection caused by susceptible bacteria, acute sinusitis gonococcal and non gonococcal urethritis in males, uncomplicated UTI skin soft tissue infections, ENT infections.	11-11-1996

216	i)Ceftibuten 200mg/400mg Capsule ii)Ceftibuten (on reconstitution) 90mg/180mg per 5ml Suspension	Upper respiratory tract infection, lower respiratory tract infections, UTI and enteritis and gastroenteritis.	19-11-1996
217	Povidone Iodine IP 5.0% w/v per ml Sterile Ophthalmic Prep Solution	For prepping of the periocular region and irrigation of the ocular surfaces.	22-11-1996
218	Fotemustine Powder 208mg (with solven) per vial i.v Injection	In the treatment of disseminated malignant melanoma including cerebral localisation and primary malignant cerebral tumours.	23-12-1996
219	Nicorandil 5mg/10mg/20mg Uncoated Tablet	For the prevention and long term treatment of angina pectoris.	10-1-1997
220	Complex 15 Cream	Phospholipid-for the treatment/immediate relief of mild to moderate to severe dry skin as is associated with xerosis, dry eczema, senile dry skin, ichthyosis neurodermatitis sputitic as adjuvant therapy in atopic eczema.	10-1-1997
221	i)Ornidazole 500mg Tablet ii)Ornidazole 5mg/ml Infusion (100ml infusion bottle)	In the treatment of susceptible protozoal infections and anaerobic bacterial infections only.	13-1-1997
222	Arteether 150mg per ampoule i.m Injection	Promoted for use in severe malaria including cerebral malaria and as a second line in chloroquine resistant malaria	14-1-1997

		cases only.	
223	Moxidectin 1% w/v Injection (For Veterinary)	In the treatment and control of internal and external parasites in cattle.	16-1-1997
224	Creatine Phosphate 500mg/1gm per vial Injection	Endogenous biochemical substance- Deficient striated muscle activity, coadjuvant in the treatment of myocardial disorders for addition to cardioplegic solution as a means of protection in heart surgery.	20-1-1997
225	i)Sodium Picosulphate 5mg/10mg Uncoated Tablet ii)Sodium Picosulphate 5mg/5ml Syrup	Constipation bowel clearance before labour or surgery, radiological examination.	11-2-1997
226	Tiaprost Trometamol 150mg Injection (For Veterinary)	In inducing parturition in cows & buffalos.	19-2-1997
227	Teicoplanin 100mg/200mg/400mg per vial i.v/i.m Injection	Glycopeptide antibiotic-use in serious gram +ve infection, staphylococcal infection in patients sensitive or unresponsive to penicillin and cephalsporins CAPD related peritonitis, prophylaxis in orthopaedic surgery at risk of gram +ve infections.	19-2-1997
228	Mefloquine Hcl 250mg Film Coated Tablet	Used in severe malaria including cerebral malaria and as a second line chloroquine resistant malaria cases only.	3-3-1997
229	Acarbose 50mg/100mg Tablet	Insulin dependent (type-II) diabetes inadequately	6-3-1997

		controlled by diet/or oral hypoglycaemic agent.	
230	Desonide 0.05% Cream	For relief of the inflammatory and pruritic manifestation of corticosteroid responsive dermatosis.	7-3-1997
231	Norfloxacin USP 100mg per gm Powder 10% (For Veterinary)	Wide variety of infections caused by susceptible gram +ve and gram -ve organism including mixed infection in poultry.	12-3-1997
232	Nicorandil 2mg/12mg/48mg i.v Injection	For the prevention and long term treatment of angina pectoris.	26-3-1999
233	Resperidone 1mg/2mg/3mg/4mg Film Coated Tablet	Acute and chronic schizophrenic psychosis and other psychotic conditions in which +ve symptoms and -ve symptoms are prominent.	3-4-1997
234	Etodolac BP 200mg/400mg Tablet and Etodolac 300mg Capsule	Inflammation and painful conditions in osteoarthritis, acute attacks of gout and pseudogout, pain following dental extraction, post operative and post episiotomy pain dysmenorrhoea acute musculoskeletal pain.	10-4-1997
235	Midazolam BP 1mg/ml per vial (5ml/10ml) Injection Midazolam 5mg/ml ampoule Prefilled Syringe	Anaesthetic general-For preoperative sedation for conscious sedation prior to short diagnostic or endoscopic procedure and for induction of general anaesthesia prior to	15-4-1997

		administration of another anaesthetic agent.	
236	Polyvidone 50mg per ml Eye Drops 5%	Symptomatic treatment of dry eye conditions including kerato-conjunctivitis sicca.	30-4-1997
237	Abciximab 10mg/5ml vial Injection		2-5-1997
238	Lacidipine 2mg/4mg Film Coated Tablet	Mild to moderate hypertension.	5-5-1997
239	Resperidone 1mg/ml Liquid	Acute and chronic schizophrenic psychosis and other psychotic conditions in which +ve symptoms and -ve symptoms are prominent.	14-5-1997
240	Diclofenac Diethyl Ammonium 174mg Plaster of 10cm x 15cm dimension		21-5-1997
241	Spenglersan Colloid G	Immunomodulator	2-6-1997
242	Pyrazinamide 250mg Dispersible Tablet	Short course treatment of tuberculosis in the paediatric age group.	6-6-1997
243	Adenosine 6mg/2ml ampoule Injection	Conversion to sinus rhythm of paroxysmal supraventricular tachycardia, including that associated with accessory by pass tracts (Wolf-Parkinson-White syndrome) when clinically advisable appropriate vagal maneuvers should be attempted prior to adenosine administration.	8-7-1997
244	Stavudine 15mg/20mg/30mg/40mg	In adult patients with advanced HIV infection who are	12-7-1997

	Capsule	intolerant of approved therapies.	
245	Azelastine Hcl 0.01gm/10ml Nasal Spray	Allergic rhinitis and perennial rhinitis.	15-7-1997
246	Azelastine 0.5mg/ml Eye Drops		5-5-2000
247	Apramycin Sulphate 50gm in each 100gm.	Bacterial enteritis cellibacillosis, salmonellosis in poultry.	22-7-1997
248	Doxepin Hcl IP 5% w/w (eq. to Doxepin 4.4%) Cream		26-7-1997
249	Prednicarbate 2.5mg per gm Cream	Skin diseases where treatment with topical corticosteroid is appropriate.	6-8-1997
250	Saquinavir Capsule	In the treatment of advanced HIV infection	26-8-1997
251	Alprazolam 1.5mg SR Tablet	Short term symptomatic treatment of anxiety including anxious patients with symptoms of depressions.	September-1997
252	Ritonavir 100mg Capsule	In the treatment of advanced HIV infection-by qualified physician not below the age of 12 years to administer.	8-9-1997
253	Serenoa Repens 160mg Lipid Extract Soft Gelatin Capsule	For BPH.	12-9-1997
254	Alendronate Sodium 10mg (as alendronic acid) Uncoated Tablet	Post menopausal osteoporosis only.	18-9-1997
255	i)Cefpodoxime Proxetil 100mg Tablet ii)Cefpodoxime Proxetil 40mg/5ml Suspension	Acute bronchitis, exacerbations of chronic bronchitis, bronchiolitis pneumonia, sinusitis, recurrent chronic	19-9-1997

		tonsillitis, pharyngitis, acute otitis.	
256	Calcium Dobesilate 500mg Capsule	Chronic venous insufficiency of lower limbs only.	22-9-1997
257	Simvastatin 5mg/10mg/20mg/40mg Tablet	Primary hypercholesterolemia, type IIa & IIb alone or in association with CAD.	25-9-1997
258	Diclofenac Sodium 100mg (Adults) & 12.5mg (Children) Suppository		26-9-1997
259	Cefpirome Sulfate 0.25g/0.5g/1.0g/2g per vial Injection	Infections caused by cefpirome sensitive organisms, lower respiratory tract infection, complicated upper and lower urinary tract infections bacteraemia/septicaemia.	26-9-1997
260	Idebenone 30mg Sugar Coated Tablet	In the treatment or improvement of decreased volition, emotional disturbance and speech disturbances associated with sequelae of cerebral infarction, sequelae of cerebral haemorrhage, cerebral arteriosclerosis.	26-9-1997
261	Doramectin 10mg/ml Injectable Solution 1% (For Veterinary)	Treatment and control of gastrointestinal round worms, lung worms, eye worm, screw worms in cattle.	17-10-1997
262	Riluzole Tablets	In the treatment of patients with amyotrophic lateral sclerosis (motor neurone disease).	17-10-1997
263	Flumethrin 1gm/100ml	Management of all tick species	29-10-1997

	Solution 1% (For Veterinary)	on the body of cattle.	
264	Clobazam 5mg/10mg/20mg Tablet	Acute and chronic anxiety states and as an adjunctive therapy in patients with refractory epilepsy.	11-11-1997
265	PEG-Electrolytes (iso-osmotic laxative)	Short term treatment of chronic constipation.	19-12-1997
266	i)Bifonazole 0.01gm/1gm Cream/Powder ii)Bifonazole 0.01gm/1ml Solution	Skin mycosis caused by dermatophytes, yeast moulds, other fungi.	28-11-1997
267	Monocomponent Insulin Lispro 40 Iu/ml (rDNA origin) per 10ml vial Injection		1-12-1997
268	Leuprolide Acetate 3.75mg per vial Depot for Injection	Indicated for the treatment of prostatic cancer only.	10-12-1997
269	i)Lyophilized S.bouardii- 282.5mg Sachet ii)Lyophilized S.bouardii- 282.5mg Capsule	i)-For irritable bowel syndrome, ii)-antibiotic associated diarrhoea, iii)-diarrhoea due to enternal feeding in adults only.	18-12-1997
270	Isepamicin Sulfate 100mg/250mg per ml Injection	LRTI, intra abdominal infection, UTI, skin & soft tissue infection and septicemia.	26-12-1997
271	Tramadol SR		27-1-1998
272	DPT ActHIB Vaccine		January-1998
273	Fluconazole 0.3% w/v per ml Eye Drops	For fungal corneal, ulcers/keratitis only.	4-2-1998
274	i)Somatropin (rDNA) 4IU/16IU per vial Injection ii)Somatropin (rDNA) 18IU/36IU/72 IU per cartridge Injection	Long term treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone	4-2-1998

		and for treatment of short stature in children with Turner's syndrome confirmed by chromosomal analysis.	
275	Hepatitis A (GBM strain) virus-160 antigen unit per 0.5ml dose	For active immunization against infection caused by hepatitis A virus	5-2-1998
276	Clotrimazole IP 100mg Soft Gelatin Pessary	Vaginal candidiasis.	17-2-1998
277	Estradiol Valerate 1mg/2mg Tablet		2-3-1998
278	Tolfenamic Acid 200mg Capsule	Rheumatoid arthritis, osteo arthritis, ankylosing spondylitis and related conditions associated with pain.	4-3-1998
279	Semduramicin Sodium 50gm per kg Premix 5% (For Veterinary)		4-3-1998
280	Melatonin 3mg Tablet	For sleep disorders Jet lag and regulation of circadium rhytham disorders.	12-3-1998
281	Letrozole 2.5mg Film Coated Tablet	Second line treatment of advanced breast cancer in women.	12-3-1998
282	i)Lamivudine 150mg/100mg Uncoated Tablet ii)Lamivudine 50mg/25mg per 5ml Oral Solution	As an adjunct to other anti retroviral agents in progressive HIV infection and chronic hepatitis B virus (HBV).	27-3-1998
283	Biphenyl Acetic 3.00% w/w per 15gm tube Gel	For the relief of symptoms of soft tissue injuries, extra articular rheumatic or inflammatory conditions, acute inflammatory manifestations of	27-4-1998

		osteoarthritis of knee joint pain, and swelling following injury.	
284	Toltrazuril-2.5gm per 100ml Solution (For Veterinary)		30-4-1998
285	Ciprofibrate 100mg Tablet	Indicated in treatment of primary hyperlipidaemia resistant to appropriate dietary management including cholesterolaemia, hypertriglyceriaemia and hyperlipidaemia (Fredrickson types IIa, IIb, III and IV)	1-5-1998
286	Collagen with Gentamicin Implant	Control of infection in surgical procedures, bone marrow, osteomyelitis, osteitis loosened prosthesis, osteosynthesis, spondylodiseitis, facial bone defect, soft tissue rectal amputation vascular graft surgery, colostomy surgery.	6-5-1998
287	Latanoprost 50mcg/ml Eye Drops	In the treatment of glaucoma and ocular hypertension.	12-5-1998
288	Lamotrigine 25mg Tablet	Add on therapy for partial and secondary generalised tonic-clonic seizures in adults not below 16 years of age.	14-5-1998
289	Propofol 10mg per ml Injection	Induction and maintenance of general anaesthesia.	18-5-1998
290	Sertraline Hcl 50mg/100mg Tablet	Major depressive disorders, obsessive compulsion disorders (OCD), panic disorders.	9-6-1998
291	Sertraline Hcl 25mg Tablet	For panic disorder only.	9-6-1998

292	Losartan Potassium 25mg/50mg/100mg Film Coated Tablet	Mild to moderate hypertension.	16-6-1998
293	Varicella Vaccine	For active immunization against varicella of healthy subjects from the age of 12 months onwards.	19-6-1998
294	Lomefloxacin Hcl 3mg/ml Eye Drops	Bacterial infection of the eye.	22-7-1998
295	Rivastigmine Hydrogen Tartrate 0.5mg/1mg/1.5mg/3mg/4mg/ 5mg/6mg Capsule	Treatment of patients with mild to moderate dementia of Alzheimer type.	31-7-1998
296	i)Oxybutynin Chloride 2.5mg/5mg Uncoated Tablet ii)Oxybutynin Chloride 2.5mg/5ml Syrup	For urinary incontinence, urgency and frequency in the unstable bladder, whether due to neurogenic bladder disorders or idiopathic detrusor instability and nocturnal enuresis.	3-9-1998
297	Fexofenadine Hcl 120mg/180mg Tablet	In the treatment of relief of symptoms associated with seasonal allergic rhinitis and chronic idiopathic urticaria in adults only.	16-9-1998
298	Carvedilol 12.5mg/25mg Tablet	Essential hypertension only.	16-10-1998
299	Oxaliplatin 50mg/100mg per vial Freeze Dried Powder for i.v Injection	For the treatment of advanced colorectal cancer.	26-10-1998
300	Vindesine Sulphate 1mg/5mg per vial Injection	Acute lymphocytic leukemia of childhood resistant to vincristine sulphate. Non	28-10-1998

		Hodgkin's lymphomas, malignant melanoma, non-small cell carcinoma of the lung, blast crisis of chronic granulocytic leukemia and carcinoma of the breast.	
301	Cephalexin Anhydrous 375mg/750mg ER Film Coated Tablet		17-11-1998
302	Pantoprazole Sodium Sesquihydrates 40mg/20mg Gastro Resistant Tablet	For the treatment of gastric ulcer, duodenal ulcer, moderate and severe reflux oesophagitis.	9-12-1998
303	Zidovudine 300mg Tablet	For HIV.	18-12-1998
304	Iron Sucrose Complex i.v Injection	All cases of iron deficiency in which rapid and reliable substitution of iron is required.	2-1-1999
305	Fentanyl Transdermal 10,20,30,40cm ² patch containing 2.5/5.0/7.5/10mg of Fentanyl delivers 25/50/75/100mcg of Fentanyl per hour respectively.	For the management of chronic cancer pain and intractable pain requiring opioid analgesics.	11-1-1999
306	Glimepiride 1mg/2mg/3mg/4mg Tablet	Adjunct to diet or exercise to lower the blood glucose in patients with non insulin dependent (type-II) diabetes mellitus whose hyperglycemia cannot be controlled by diet and single agent alone.	24-1-1999
307	Leprosy Immunomodulator Vaccine (based on MW)		9-2-1999
308	Mycophenolate Mofetil 250mg/500mg Capsule/Tablet		7-2-1999

309	Meloxicam 7.5mg/15mg Uncoated Tablet	For the treatment of rheumatoid arthritis and osteoarthritis.	16-2-1999
310	Tetrabenazine 25mg Tablet	In treatment of movement disorders associated with organic CNS conditions like Huntington's chorea, hemiballismus and senil chorea.	10-3-1999
311	Buprenorphine Hcl 0.4mg/2mg Uncoated Tablet	For opioid de-addiction.	10-3-1999
312	Carvedilol 3.125mg/6.25mg (new strength)	In treatment of congestive heart failure (CHF).	10-3-1999
313	Doxazocin Mesylate 1mg/2mg/4mg Uncoated Tablet	Mild to moderate hypertension only.	11-3-1999
314	Prazosin Mesylate	Mild to moderate hypertension only.	11-3-1999
315	Nafarelin Acetate 2mg/1ml Nasal Spray	Endometriosis and central precarious puberty only (for gynaecologist only)	17-3-1999
316	MMR Vaccine		26-3-1999
317	Nabumetone 500mg/750mg Film Coated Tablet	Osteoarthritis & rheumatoid arthritis.	17-5-1999
318	Ketoprofen 30mg Transdermal Patch	For the relief of musculoskeletal pain & inflammation.	17-5-1999
319	Nimesulide 50mg/100mg/200mg Suppository		17-5-1999
320	Milrinone (as Lactate) 1mg/ml solution Injection	In short term treatment of severe congestive heart failure irresponsive in to conventional	17-5-1999

		maintenance therapy and in acute heart failure including low output state following surgery.	
321	Brimonidine Tartrate 0.2% (eq. to Brimonidine base 0.13%) Ophthalmic Solution	For lowering intraocular pressure in patients with open angle glaucoma or ocular hypertension.	18-5-1999
322	Zolpidem Hemitartrate 5mg/10mg Film Coated Tablet	Short term treatment of insomnia.	28-5-1999
323	Basiliximab Injection	For the prophylaxis of acute organ rejection in de-novo transplantation & is to be used concomitantly with cyclosporin for microemulsion & corticosteroid immuno suppression.	28-5-1999
324	Topotecan Hcl 4mg/vial Injection Concentrate	Metastatic ovarian cancer after failure of first line chemotherapy.	15-6-1999
325	Diazepam IP 2mg/4mg per ml Rectal Solution	Emergency treatment of convulsions as well as chronic prophylaxis against febrile seizures.	17-6-1999
326	Fludarabine Phosphate 50mg (eq. to 39.05mg of fludarabine) per vial i.v Injection	The treatment of patients with B-cell chronic lymphocytic leukaemia (CLL) who have not responded to at least one standard alkylating agent containing regimen.	22-6-1999
327	Pilocarpine Hcl 40mg/gm Gel	For the management of intraocular pressure in glaucoma.	24-6-1999

328	Sodium Valporate Freeze Dried Powder 400mg/ml Injection	In treatment of generalised epilepsy as well as for partial epilepsy in patients for whom oral therapy is temporarily not possible.	20-7-1999
329	i)Levofloxacin 250mg/500mg Film Coated Tablet ii)Levofloxacin 5mg/ml (in 50ml & 100ml) Infusion	In treatment of acute maxillary sinusitis, acute bacterial exacerbation, chronic bronchitis, community acquired pneumoniae, skin & soft tissue infection, complicated urinary tract infection or acute pyelonephritis.	26-7-1999
330	i)Zuclopenthixol Acetate 50mg/200mg per ml Injection ii)Zuclopenthixol 25mg Film Coated Tablet	By psychiatrist only- treatment of acute psychosis including mania & exacerbation of chronic psychosis acute & chronic schizophrenia.	29-7-1999
331	Menadione Sodium Bisulphite 1mg/0.5ml Injection		6-8-1999
332	Hydrocortisone (10% w/w) Enema Foam	For adjunctive therapy in the topical treatment of ulcerative proctitis of the distal portion of the rectum in patients of ulcerative colitis & proctosigmoiditis.	9-8-1999
333	Prochlorperazine Maleate 3mg Buccal Tablet	For treatment of nausea, vomiting, post operative emesis & migraines.	9-8-1999
334	r-Follicle Stimulating Hormone (FSH)		19-8-1999
335	Hyoscine-N-butyl Bromide	In treatment of gastrointestinal	23-8-1999

	7.5mg/10mg Suppository	tract spasm, spasm & dyskinesia of the biliary system genito urinary tract spasm.	
336	i)Topiramate 25mg/50mg/100mg/200mg/ 300mg/400mg Tablet ii)Topiramate 25mg/50mg Sprinkle Capsule	In the treatment of partial and generalized tonic clonic seizures.	23-8-1999
337	i)Eptifibatide 2mg/ml per 10ml vial Injection ii)Eptifibatide 0.75mg/ml per 100ml vial Injection	In treatment of patients with acute coronary syndrome & patients undergoing percutaneous coronary intervention.	25-8-1999
338	Prazocin GITs 2.5mg Tablet	In additional indication of B.P.H.	14-9-1999
339	Omeprazole Magnesium 10mg/20mg Enteric Coated Tablet		17-9-1999
340	Atorvastatin Calcium 10mg/20mg/40mg Film Coated Tablet	As an adjunct diet to reduce elevated total cholesterol and triglyceride levels in patients with primary hypercholesterolemia and mixed dyslipidemia (type IIa & IIb).	17-9-1999
341	Bleomycin Sulphate 5mg/gm Ointment	For malignant skin tumour.	11-10-1999
342	Sulpiride 50mg/200mg Capsule	In treatment of mild to moderate depression and neurotic depression.	26-10-1999
343	Certoparin Sodium 3000 IU per disposable syringe of 0.3ml	For thromboembolism prophylaxis only.	October-1999

	solution Injection		
344	i)Bambuterol Hcl BP 10mg/20mg Uncoated Tablet ii)Bambuterol Hcl 1mg/ml Oral Suspension	Bronchodilator.	13-12-1999
345	Fenofibrate 200mg (micronized) Capsule	For type IIa, IIb, III, IV & V hyper lipidaemias resistant to diet.	22-12-1999
346	Sibutramine Hcl Monohydrate 5mg/10mg/15mg Capsule	Adjunct therapy for the management of obesity including weight loss and maintenance of weight loss in patients whose BMI is 30kg/m ² or higher.	23-12-1999
347	Lamivudine 25mg/5ml Oral Solution	For the treatment of chronic hepatitis B virus infection.	30-12-1999
348	'Biomesh' GTR barrier (biodegradable)	An aid to promote regeneration and integration of peridental tissue components after surgical procedure.	1-12-1999
349	Bulaquine Compound 80/53	For vivax malaria only.	21-12-1999
350	Oxiconazole Nitrate 1% w/v Cream & Lotion	For topical treatment of superficial fungal infections of the skin.	17-1-2000
351	Temozolamide 5mg/20mg/100mg/250mg Capsule	For the treatment of adult patients with recurrent malignant glioma such as glioblastoma multiforme or anaplastic astrocytoma.	17-1-2000
352	Betahistine Hcl 16mg Tablet		20-1-2000
353	Lamotrigine 50mg/100mg Tablet		21-1-2000
354	Infliximab 100mg/10ml vial i.v	For treatment of moderate to	25-1-2000

	Injection	severely active Crohn's disease for the reduction of signs and symptoms in patients who have an inadequate response to conventional therapies.	
355	Olanzapine 5mg/7.5mg/10mg/2.5mg Tablet	For treatment of schizophrenia in adults.	27-1-2000
356	Erythromycin 300mg/6ml single pack Intramammary Infusion (For Veterinary)	For treatment of mastitis in lactating cows only.	7-2-2000
357	Recombinant Human Erythropoietin (r-Hu Epo)	For additional indication of autologous blood donation in case of anaemia due to chronic renal failure and anaemia associated with cancer.	7-2-2000
358	i)Formoterol Fumerate 12mcg Capsule (Rotacap) ii)Formoterol Fumerate 12mcg Inhaler	For bronchial asthma.	18-2-2000
359	Fluvoxamine Maleate 50mg/100mg Film Coated Tablet	In treatment of obsessive compulsive disorder and depression.	21-2-2000
360	Celecoxib 100mg/200mg Capsule	For treatment of R.A & O.A.	22-2-2000
361	Collagen Fleece	For surgical procedure.	2-3-2000
362	Ticlopidine	Additional indication- prevention of sub-acute occlusion following coronary stent implantation.	3-3-2000
363	i)Nevirapine 200mg Tablet ii)Nevirapine 50mg/5ml Suspension	For HIV infection in combination with other anti retroviral agents.	6-3-2000

364	Alendronate Sodium 5mg		6-3-2000
365	Clotrimazole 10mg Lozenges	For local treatment of oropharyngeal candidiasis in immuno compromised patients.	13-3-2000
366	Enoxaparin Sodium Injection	For additional indication- prophylaxis of deep vein thrombosis.	16-3-2000
367	Ripaglinide 0.25mg/0.5mg/1.0mg/2mg Tablet	Treatment of type-II diabetes (NIDDM) whose hyperglycemia can no longer be controlled satisfactorily by diet, weight reduction and exercise.	23-3-2000
368	MMR Vaccine		29-3-2000
369	Levo-Carnitine 1gm per single dose (5ml ampoule) Injection		31-3-2000
370	Piroxicam Transdermal Patch		March-2000
371	i)Ganciclovir 250mg Capsule ii)Ganciclovir 500mg per vial Injection	For the prevention & treatment of cytomegalo virus disease in immuno compromised individuals and for the prevention of CMV disease in transplant recipients..	5-4-2000
372	Ketotifen Fumerate 0.25mg/ml Eye Drops	For temporary prevention of itching of the eyes due to allergic conjunctivitis.	5-5-2000
373	Lincomycin Hcl 2% w/w Gel	For acne vulgaris.	11-5-2000
374	i)Trapidil 100mg/200mg Capsule ii)Trapidil 50mg/ml Injection	For prevention of restenosis after percutaneous transluminai coronary angioplasty (PTCA) in patients of athero sclerosis arterial disease.	11-5-2000
375	Cerivastatin Sodium	By RMP- primary	11-5-2000

	100mcg/200mcg/300mcg Tablet	hypercholesterolemia type IIa, IIb resistant to diet.	
376	Roxithromycin 75mg Tablet	For paediatric use.	15-5-2000
377	Amoxicillin 3H ₂ O 200mg/400mg Dispersible Tablet		26-5-2000
378	Fluconazole 50mg/5ml Oral Suspension	For systemic candidiasis, mucosal candidiasis, cryptococcosis, prevention of fungal infection in patients with malignancy.	29-5-2000
379	Combination Vaccine DPT + Hi-b	For active immunization of children two months-five year of age against diptheria, tetanus, pertusis and haemophilus influenza type-b disease when indication for immunization with DTP vacc & Hib conjugate vaccine coincide and is not to be used for treatment of actual infection.	1-6-2000
380	Pantoprazole Sodium 40mg per vial i.v Injection	Deodenal ulcer, gastric ulcer, moderate and severe reflux oesophagitis.	7-6-2000
381	Sodium Dichloro Isocyanurate 35mg/350mg/1.75g/3.5g Tablet	For chlorination of drinking water.	12-6-2000
382	r Human Erythropoeitin 1000IU/ml, 2000IU/ml, 3000IU/ml, 4000IU/ml, 10000IU/ml Injection	For additional indication of perisurgery	19-6-2000
383	Rofecoxib 12.5mg/25mg	By RMP- for osteoarthritis,	26-6-2000

	Uncoated Tablet	acute pain, dysmenorrhoea only.	
384	Irbesartan 75mg/150mg/300mg Uncoated Tablet	By RMP- for the treatment of mild to moderate hypertension only.	26-6-2000
385	Cyclosporin 10mg Capsule	As additional strength.	27-6-2000
386	Rosiglitazone Maleate 1mg/2mg/4mg/8mg Film Coated Tablet	By RMP- for treatment of type-II diabetes mellitus as mono therapy & adjunct to diet.	28-6-2000
387	Methyl Hydroxy Propyl Cellulose 0.3% Eye Drops	By RMP- for temporary relief of discomfort due to minor irritation of the eye from exposure to wind sun or other irritants for use as a protectant against further irritation or to relief dryness of then eyes.	5-7-2000
388	i)Granisetron Hcl 1mg/2mg Film Coated Tablet ii)Granisetron Hcl 1mg/ml Injection	By RMP- for nausea vomiting in cancer patients treated with cytotoxic drugs.	5-7-2000
389	Rituximab 10mg/ml vial (Concentrate for solution for infusion)	By cancer specialist-for the treatment of patients with relapsed or chemo resistant indolent B cell Non-Hodgkin's lymphomas.	10-7-2000
390	Trastuzumab 440mg/vial Powder Concentrate Infusion	By cancer specialist-in metastatic breast cancer who have tumours that over express human epidermal growth factor receptor-2 (HER2).	10-7-2000
391	Recombinant Human Erythropoietin (r Hu Epo)	For additional indication- anaemia associated with	12-7-2000

		cancer.	
392	Amphotericin B (USP) 5mg/ml per 10ml/20ml Lipid Complex Injection	By RMP- for the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional amphotericin-B therapy.	12-7-2000
393	Rosiglitazone 2mg/4mg/8mg Tablet	For additional indication of "in combination with suphonyl urea or metformin when diet, exercise and rosiglitazone alone or diet, exercise plus the single agent do not results in adequate glycemic control".	14-7-2000
394	Sodium Valporate Tablet/Syrup	For additional indications- manic episodes associated with bipolar disorders.	17-7-2000
395	Synthetic Salmon Calcitonin 50IU/100IU/200IU Nasal Spray	By RMP- in post menopausal osteoporosis, bone pain associated with osteolysis and/or osteopenia Paget's disease.	18-7-2000
396	Moclobemide 150mg/300mg Film Coated Tablet	By psychiatrist- major depression & social phobia.	28-7-2000
397	Insulin Lispro Mixtures (rDNA) Injection	Already approved for different mixtures, diabetes mellitus.	31-7-2000
398	Candesartan Cilxetil 4mg/8mg/16mg Tablet	By RMP- for mild to moderate essential hypertension only.	31-8-2000
399	Levonorgestrel 52mg Sterile Intra Uterine System	By RMP- contraception, menorrhagia & endometrial hyperplasia during estrogen replacement therapy in women.	13-9-2000
400	rDNA Hepatitis B Vaccine (10mcg)		15-9-2000

401	Venlafaxine Hcl 25mg/37.5mg/75mg Uncoated Tablet	By psychiatrist only- for major depression only.	18-9-2000
402	Rofecoxib 12.5mg/25mg per 5ml Oral Suspension		25-9-2000
403	Bambuterol Hcl 1mg/ml Oral Suspension	By RMP- for bronchospasm in asthma reversible airway disease for children > age of 2 years.	27-9-2000
404	Doramectin 1% Injectable Solution (For Veterinary)	For control of GI round worm, eye worm, screw worms in sheep & swine.	3-10-2000
405	Paroxetine Hcl 10mg/20mg/30mg/40mg Tablet	By psychiatrists only- for major depression, obsessive compulsive disorders and panic disorders.	4-10-2000
406	Iomeprol corresponding to 300mg/400mg Iodine per ml Injection	For use in hospitals, nursing home, institution only. For use in intravenous urography C/T (Brain & Body)	5-10-2000
407	Venlafaxine Hcl 37.5mg/75mg/150mg S.R Capsule	Major depression.	6-10-2000
408	Pergolide Mesylate 50mcg/250mcg/1000mcg Tablet	By neurologists- adjunctive treatment to levodopa in management of the signs & symptoms of Parkinson's disease.	11-10-2000
409	Capecitabine 150mg/500mg Film Coated Tablet	By cancer specialists- for treatment of metastatic breast cancer after failure of paclitaxel and anthracycline containing chemotherapy	12-10-2000

		regimen.	
410	Daclizumab 25mg/5ml vial Solution for Infusion	By hospital, nursing homes, institution only. For prophylaxis in acute organ rejection in patients receiving transplants.	12-10-2000
411	Pioglitazone Hcl 15mg/30mg/45mg Uncoated Tablet	As an adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes (NIDDM)	17-10-2000
412	Hepatitis B surface antigen (HBsAg) 20mcg/ml,100mcg/100ml, 10mcg/0.5ml per vial Hepatitis-B Vaccine (recombinant)	For active immunization against Hepatitis-B	31-10-2000
413	Fexofenadine Hcl 60mg/30mg Tablet	By RMP- 30mg for relief of seasonal allergic rhinitis in children (6-12yrs), 60mg tab for relief of chronic idiopathic urticaria in 12yrs age and older children.	1-11-2000
414	Gliclazide 30mg Modified Release Tablet	By RMP- in treatment of NIDDM (type-II) in association with dietary measures in adult only.	4-11-2000
415	Amifostine Injection	Additional indication- for use in association with standard fractionated radiation therapy to protect against acute and late xerostomia in hand and neck cancer.	6-11-2000
416	rHuman Erythropoietin	For hospitals/institutions &	8-11-2000

	2000IU/4000IU per vial Injection	prescription of cancer specialist for anaemia due to chronic renal failure, anaemia associated with cancer & cancer chemotherapy, HIV infected patients on zidovudine, adult surgery patients in autologus pre-donation program and peri-surgery patients without blood donation.	
417	Didanosine 25mg/50mg/100mg Chewable Tablet	By RMP- HIV infection when anti-retroviral therapy is wanted.	15-11-2000
418	Fluticasone Propionate B.P 0.5mg/2.0mg per 2ml Respule	By RMP- for the prophylactic management of severe chronic bronchial asthma in patients requiring high dose inhaled or oral corticosteroid therapy.	27-11-2000
419	Liposomal Doxorubicin Hcl 2mg/ml Pegylated Injection	Additional indication-for the treatment of metastatic carcinoma of the ovary in patients with diseases, refractory to both paclitaxel and platinum based chemotherapy.	29-11-2000
420	Otilonium Bromide 40mg Tablet	By RMP- in treatment of irritable bowel syndrome, painful spastic condition of distal enteric tract.	15-12-2000
421	Pravastatin Sodium 10mg/20mg/40mg Uncoated Tablet	By RMP- primary hypercholesterolemia type IIa, IIb and prevention of	20-12-2000

		cardiovascular events in adults only.	
422	Somatropin (r human growth hormone) 24IU/8mg	By endocrinologists- growth failure due to inadequate secretion of normal endogenous growth hormone.	20-12-2000
423	Beclomethasone Dipropionate 50mcg/100mcg/250mcg Inhaler	By RMP- for treatment of asthma.	21-12-2000
424	Recombinant Interferon Alpha-2b 3mIU/5mIU/10mIU/18mIU/25mIU Injection	For use in cancer-hospital/institution and against the prescription of specialists only- for multiple myeloma, AIDS related kaposi sarcoma, malignant melanoma, hairy cell leukemia, chronic myelogenous leukemia, laryngeal papillomathesis, condylomata, acuminata, superficial and nodulo ulcerative basal cell carcinoma chronic hepatitis-B and hepatitis-C.	27-12-2000

Note: The above list of approved New Drugs is prepared as per the records available with this office. If discrepancy is observed, the same may be brought to the notice of this office along with documentary evidence for necessary action.