<u>LIST OF NEW DRUGS APPROVED IN INDIA FROM 1991 TO 2000</u>

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

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

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

	ovtomal infactions of the	
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	•	
	susceptible bacteria.	
Clomipramine Hcl	Anti depressant- Obsessive	February-1992
10mg/25mg/50mg Tablet	compulsive disorders, phobic	
	states and depression (when	
	sedation is required).	
Clomipramine Hcl 50mg	Anti depressant- Obsessive	February-1992
Capsule	compulsive disorders, phobic	
	states and depression (when	
	sedation is required).	
Bisoprolol Fumerate (2:1)	Anti hypertensive-	27-2-1992
5mg/10mg Film Coated Tablet	Hypertension, coronary heart	
	disease (angina pectoris).	
Amsacrine Injection	Anti cancer.	26-2-1992
Fusidic Acid BP 10mg/gm Eye		3-3-1992
Drops		
Fusidic Acid Hemihydrate Eye	Bacterial infection of the eye	March-1992
Drops	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.	
i)Roxithromycin	Antibiotic- Sensitive strain	27-3-1992
150mg/300mg Film Coated	infections of ENT,	
Tablet	bronchopulmonary tract	
ii)Roxithromycin 50mg Kid	infection, genital except for	
Tablet	gonococcal infections,	
iii)Roxithromycin 50mg	prophylaxis of meningococcal	
Dispersible Tablet	meningitis in exposed subjects.	
iv)Roxithromycin 50mg/5ml		
	Clomipramine Hcl 50mg Capsule Bisoprolol Fumerate (2:1) 5mg/10mg Film Coated Tablet Amsacrine Injection Fusidic Acid BP 10mg/gm Eye Drops Fusidic Acid Hemihydrate Eye Drops i)Roxithromycin 150mg/300mg Film Coated Tablet ii)Roxithromycin 50mg Kid Tablet iii)Roxithromycin 50mg Dispersible Tablet	Clomipramine Hcl 50mg Anti depressant- Obsessive compulsive disorders, phobic states and depression (when sedation is required). Clomipramine Hcl 50mg Capsule Capsule Compulsive disorders, phobic states and depression (when sedation is required). Bisoprolol Fumerate (2:1) Anti hypertensive-sedation is required). Bisoprolol Fumerate (2:1) Anti hypertensive-states and depression (when sedation is required). Anti hypertensive-states (angina pectoris). Anti cancer.

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

	Dimeglumine Salt	spinal magnetic resonance	
	469.01mg/ml Injection	tomography.	
42	Pyridoxine Hcl 100mg C.R	Deficiency of vit.B6 caused by	7-5-1992
	Tablet	usage of oral contraceptive	
		pill/drug induced pyridoxine	
		deficiency.	
43	Cephacetrile Sodium 235mg in	Mastitis caused by	13-5-1992
	10gm of suspension	streptococcus agalactial, str.	
	Intramammary Infusion (For	dysgalactial, str. Uberis, str.	
	Veterinary)	Aureus (both penicillin-	
		sensitive and resistant strain)	
		gram negative bacterial	
		including E. coli and klebsiella.	
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	Disinfectant instrument.	20-5-1992
	Instrument Disinfectant		
47	Sterillium Rub in Disinfectant	Disinfectant for hands.	20-5-1992
	for Hands.		
48	Bacillocid Special	Disinfectant surface.	20-5-1992
49	Loratidine 10mg Tablet	Long acting anti histaminic- In	19-6-1992
		treatment of allergic rhinitis,	
		acute coryza, chronic	
		idiopathic urticaria.	
50	Dexfenfluramine Hcl 15mg	Anti obesity drug- Indicated in	22-6-1992
	Capsule	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).	
51	Bacillus Calmette and Geurin	Anti cancer- To be indicated	22-6-1992

	(Immucyst, BCG therapeutics)	for intravesical use in the	
	27mg dry weight per Vaccine	treatment of primary and	
		relapse carcinoma in-situ of the	
		urinary bladder.	
52	Candur P. Parvovirus Vaccine	Indicated in active	9-7-1992
	(For Veterinary)	immunization of dogs against	
		parvovirus infection.	
53	Naloxone Hcl	Indicated for the complete	28-7-1992
	0.02mg/0.4mg/1.0mg per ml	partial reversal of narcotic	
	(i.v/i.m/s.c) Injection	depression including	
		respiratory depression, induced	
		by opioids including natural	
		and synthetic narcotics,	
		propoxyphene methadone, and	
		certain narcotic-antagonist	
		analgesics, nalbuphine,	
		pentazocin and butorphenol.	
54	i)Nimodipine 30mg Tablet	In the treatment and prevention	31-8-1992
	ii)Nimodipine 10mg/50ml	of ischaemic neurological	
	Injection	deficit occuring due to arterial	
	iii)Nimodipine 30mg Soft	spasm, following sub	
	Gelatin Capsule	arachnoid haemorrhage.	
55	Ginko Biloba 40mg Film	Herbal extract- In treatment of	8-9-1992
	Coated Tablet	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.	
			0 1 1000
56	Hamycin 0.1% per gm Hair		September-1992
56	Hamycin 0.1% per gm Hair Cream		September-1992

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

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

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

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

	Dispersible Tablet		
97	Diclofenac Sodium 50mg		30-9-1993
		idiopathic Parkinson's disease.	
		symptoms of arterial disease,	
		giddiness in elderly, pain full	
	Tablet	and/or memory or feelings of	
96	Piribedil 50mg S.R Coated	Of impaired attentiveness	27-9-1993
	Capsule		
	divinyl benzene Soft Gelatin		
	Ca++) cross linked with 8%		
	resin 0.5gm (eq. to 1.8mEq		
	polystyrene cation exchange		
95	Calcium loaded sulfonated		13-9-1993
	Release Tablet		
94	Aspirin 325mg/500mg Delayed		6-9-1993
		level.	
	0.75gm/1.0gm/1.3gm Sachet	level reduction serum lipid	
93	Glucomannan	For reduction of blood glucose	6-9-1993
- -	Gelatin Capsule	bone disease.	
92	Calcitriol 0.5mcg/0.25mcg Soft	For the treatment of metabolic	27-8-1993
	per vial Injection		
91	Cefoperazone Sodium 1g/2g		23-8-1993
	(For Veterinary)		
30	Emryo Cell Rabies Vaccine)		13-0-1773
90	Candur-R (Purified Chick		13-8-1993
89	Zalcitabine 0.375mg/0.750mg Film Coated Tablet	For the treatment of AIDS.	26-7-1993
00	minerals	Earth Anna (CADC	26.7.1002
88	Chelated Amino Acid based	Trace mineral deficiencies.	20-7-1993
		mycoses.	
		occuring systemic or tropical	
		blastomycosis and other rarely	
		paracoccidioidomycosis,	

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

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

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

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

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

	Injection	labours after operations.	
145	Rilmenidine Dihydrogen Phosphate 1mg Tablet	Mild to moderate hypertension.	21-2-1995
146	Disodium Pamidronate	Tumour inducer	21-2-1995
	Injection	hypercalcaemia.	
147	Tromantadine Hcl 1gm	Herpes simplex infection of the	23-2-1995
	Ointment	skin.	
148	Permethrin 5% Cream	Infestation with sarcopyto	6-3-1995
		scabies.	
149	Formestane Sterile 250mg	For the treatment of advance	6-3-1995
	(i.m) Depot Injection	stage of breast cancer in	
		women with natural or	
		artificially induced post	
		menopausal status.	
150	Clozapine 25mg/100mg	Indicated in the management of	7-3-1995
	Uncoated Tablet	schzophrenic patients.	
151	Etidronate Disodium 200mg	Hypercalcemia induced by	10-3-1995
	Tablet	various malignant disorders.	
152	Altretamine 50mg Capsule	For palliative treatment of	10-3-1995
		patients with persistent or	
		recurrent ovarian cancer,	
		following first line therapy	
		with cisplatin and/or alkylating	
		agent based combination.	
153	i)Clarithromycin	Of mild to moderately severe	22-3-1995
	250mg/500mg Tablet	infections like acute	
	ii)Clarithromycin	exacerbation of chronic	
	125mg/250mg per 5ml	bronchitis community acquired	04-09-1995
	Paediatric Suspension	pneumonia including infections	
		due to chlamydia, mycoplasma	
		spegiocella acute streptococcal	
		pharyngitis and skin and soft	
		tissue infections.	

154	Terbinafine 250mg Tablet	Fungal infection of skin, hair	29-3-1995
	Terbinafine 1% Cream	nails.	
155	Somatostatin i.v Infusion	Severe acute haemorrhage	24-4-1995
		from oesophegal	
		varices/gastric or deodenal	
		ulcers or acute erosive or	
		haemorrhagic gastritis adjuvant	
		treatment in pancreatic billiary	
		and intestinal fistulae.	
		Prophylaxis and treatment of	
		postoperative complication	
		following pancreatic surgery,	
		adjuvant treat in diabetic	
		keratoacidosis.	
156	Podophyllotoxin 0.5% each	Anogenital warts, non genital	5-5-1995
	3-5ml Topical Solution	warts only.	
157	Nicotine Transdermal		17-5-1995
	Therapeutic System		
158	Tenoxicam 20mg Dispersible		31-5-1995
	Tablet		
159	Progesterone Micronized Soft		21-6-1995
	Gelatin Capsule		
160	Prazosin Hcl (GITS) Tablets		21-6-1995
161	Silymarin 70mg/140mg Sugar	For supportive treatment in	22-6-1995
	Coated Tablet	chronic liver disease and	
		cirrhosis.	
162	Naproxen 750mg C.R Tablet		26-6-1995
163	Coumarin Tablet		July-1995
164	Terlipressin Acetate1mg per	In the treatment of bleeding	22-7-1995
	vial Injection	oesophagal varices.	
165	i)Salmon Calcitonin 100 IU/ml	Hypercalcaemia pain	3-8-1995
	each ampoule Injection	associated with advanced	
	ii)Salmon Calcitonin 400	metastic bone cancer, Paget's	

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

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

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

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

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

	0.125mg/0.250mg/0.500mg	characterized by luteal	
	Tablet	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	Management of hypertension	9-10-1996
	(as pellets) Retard Capsule	and angina pectoris.	
211	Finasteride 5mg Film Coated	Benign prostatic hypertrophy	9-10-1996
	Tablet	only.	
212	Naltrexone Hcl 50mg	In the treatment of narcotic	11-10-1996
	Uncoated Tablet	antagonist and alcohol	
		dependence.	
213	Tibolone 2.5mg Tablet	In the treatment of complaints	16-10-1996
		resulting from the natural or	
		surgical menopause.	
214	Amoxycillin Trihydrate 750mg		16-10-1996
	Bolus (For Veterinary)		
215	Sparfloxacin	Community acquired	11-11-1996
	100mg/200mg/400mg Tablet	pneumonia, acute exacerbation	
		of chronic bronchitis, other	
		lower respiratory tract	
		infection caused by susceptible	
		bacteria, acute sinusitis	
		genococcal and non	
		genococcal urethritis in males,	
		uncomplicated UTI skin soft	
		tissue infections, ENT	
		infections.	

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

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

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

		administration of another	
		anaesthetic agent.	
236	Polyvidone 50mg per ml Eye	Symptomatic treatment of dry	30-4-1997
	Drops 5%	eye conditions including	
		kerato-conjunctivitissicca.	
237	Abciximab 10mg/5ml vial		2-5-1997
	Injection		
238	Lacidipine 2mg/4mg Film	Mild to moderate hypertension.	5-5-1997
	Coated Tablet		
239	Resperidone 1mg/ml Liquid	Acute and chronic	14-5-1997
		schizophrenic psychosis and	
		other psychotic conditions in	
		which +ve symptoms and -ve	
		symptoms are prominent.	
240	Diclofenac Diethyl		21-5-1997
	Ammonium 174mg Plaster of		
	10cm x 15cm dimension		
241	Spenglersan Colloid G	Immunomodulator	2-6-1997
242	Pyrazinamide 250mg	Short course treatment of	6-6-1997
	Dispersible Tablet	tuberculosis in the paediatric	
		age group.	
243	Adenosine 6mg/2ml ampoule	Conversion to sinus rhythm of	8-7-1997
	Injection	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.	
244	Stavudine	In adult patients with advanced	12-7-1997
			l

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

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

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

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

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

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

		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		17-11-1998
	375mg/750mg ER Film Coated		
	Tablet		
302	Pantoprazole Sodium	For the treatment of gastric	9-12-1998
	Sesquihydrates 40mg/20mg	ulcer, duodenal ulcer, moderate	
	Gastro Resistant Tablet	and severe reflux oesophagitis.	
303	Zidovudine 300mg Tablet	For HIV.	18-12-1998
304	Iron Sucrose Complex i.v	All cases of iron deficiency in	2-1-1999
	Injection	which rapid and reliable	
		substitution of iron is required.	
305	Fentanyl Transdermal	For the management of chronic	11-1-1999
	10,20,30,40cm2 patch	cancer pain and intractable	
	containing 2.5/5.0/7.5/10mg of	pain requiring opioid	
	Fentanyl delivers	analgesics.	
	25/50/75/100mcg of Fentanyl		
	per hour respectively.		
306	Glimepiride	Adjunct to diet or exercise to	24-1-1999
	1mg/2mg/3mg/4mg Tablet	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.	
307	Leprosy Immunomodulator		9-2-1999
	Vaccine (based on MW)		
308	Mycophenolate Mofetil		7-2-1999
	250mg/500mg Capsule/Tablet		

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

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

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

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

	solution Injection		
344	i)Bambuterol Hcl BP	Bronchodilator.	13-12-1999
	10mg/20mg Uncoated Tablet		
	ii)Bambuterol Hcl 1mg/ml		
	Oral Suspension		
345	Fenofibrate 200mg	For type IIa, IIb, III, IV & V	22-12-1999
	(micronized) Capsule	hyper lipidaemias resistant to	
		diet.	
346	Sibutramine Hcl Monohydrate	Adjunct therapy for the	23-12-1999
	5mg/10mg/15mg Capsule	management of obesity	
		including weight loss and	
		maintenance of weight loss in	
		patients whose BMI is	
		30kg/m2 or higher.	
347	Lamivudine 25mg/5ml Oral	For the treatment of chronic	30-12-1999
	Solution	hepatitis B virus infection.	
348	'Biomesh' GTR barrier	An aid to promote regeneration	1-12-1999
	(biodegradable)	and integration of peridontal	
		tissue components after	
		surgical procedure.	
349	Bulaquine Compound 80/53	For vivax malaria only.	21-12-1999
350	Oxiconazole Nitrate 1% w/v	For topical treatment of	17-1-2000
	Cream & Lotion	superficial fungal infections of	
		the skin.	
351	Temozolamide	For the treatment of adult	17-1-2000
	5mg/20mg/100mg/250mg	patients with recurrent	
	Capsule	malignant glioma such as	
		glioblastoma multiforme or	
		anaplastic astrocytoma.	
352	Betahistine Hcl 16mg Tablet		20-1-2000
353	Lamotrigine 50mg/100mg		21-1-2000
	Tablet		
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	For treatment of schizophrenia	27-1-2000
	5mg/7.5mg/10mg/2.5mg	in adults.	
	Tablet		
356	Erythromycin 300mg/6ml	For treatment of mastilis in	7-2-2000
	single pack Intramammary	lactating cows only.	
	Infusion (For Veterinary)		
357	Recombinant Human	For addition indication of	7-2-2000
	Erythropoietin (r-Hu Epo)	autologous blood donation in	
		case of anaemia due to chronic	
		renal failure and anaemia	
		associated with cancer.	
358	i)Formoterol Fumerate 12mcg	For bronchial asthma.	18-2-2000
	Capsule (Rotacap)		
	ii)Formoterol Fumerate 12mcg		
	Inhaler		
359	Fluvoxamine Maleate	In treatment of obsessive	21-2-2000
	50mg/100mg Film Coated	compulsive disorder and	
	Tablet	depression.	
360	Celecoxib 100mg/200mg	For treatment of R.A & O.A.	22-2-2000
	Capsule		
361	Collagen Fleece	For surgical procedure.	2-3-2000
362	Ticlopidine	Additional indication-	3-3-2000
		prevention of sub-acute	
		occlusion following coronary	
		stent implantation.	
363	i)Nevirapine 200mg Tablet	For HIV infection in	6-3-2000
	ii)Nevirapine 50mg/5ml	combination with other anti	
	Suspension	retroviral agents.	

364	Alendronate Sodium 5mg		6-3-2000
365	Clotrimazole 10mg Lozenges	For local treatment of	13-3-2000
		oropharyngeal candidiasis in	
		immuno compromised patients.	
366	Enoxaparin Sodium Injection	For additional indication-	16-3-2000
		prophylaxis of deep vain	
		thrombosis.	
367	Ripaglinide	Treatment of type-II diabetes	23-3-2000
	0.25mg/0.5mg/1.0mg/2mg	(NIDDM) whose	
	Tablet	hyperglycemia can no longer	
		be controlled satisfactorily by	
		diet, weight reduction and	
		exercise.	
368	MMR Vaccine		29-3-2000
369	Levo-Carnitine 1gm per single		31-3-2000
	dose (5ml ampoule) Injection		
370	Piroxicam Transdermal Patch	Osteoarthritis pain due to	16-03-2000
	48mg	musculoskeletal disorder.	
371	i)Ganciclovir 250mg Capsule	For the prevention & treatment	5-4-2000
	ii)Ganciclovir 500mg per vial	of cytomegalo virus disease in	
	Injection	immuno compromised	
		individuals and for the	
		prevention of CMV disease in	
		transplant recipients	
372	Ketotifen Fumerate 0.25mg/ml	For temporary prevention of	5-5-2000
	Eye Drops	itching of the eyes due to	
		allergic conjunctivitis.	
373	Lincomycin Hcl 2% w/w Gel	For acne vulgaris.	11-5-2000
374	i)Trapidil 100mg/200mg	For prevention of restenosis	11-5-2000
	Capsule	after percutaneous transluminai	
	ii)Trapidil 50mg/ml Injection	coronary angioplasty (PTCA)	
		in patients of athero sclerosis	
		arterial disease.	

375	Cerivastatin Sodium	By RMP- primary	11-5-2000
	100mcg/200mcg/300mcg	hypercholesterolemia type IIa,	
	Tablet	IIb resistant to diet.	
376	Roxithromycin 75mg Tablet	For paediatric use.	15-5-2000
377	Amoxycillin 3H2O		26-5-2000
	200mg/400mg Dispersible		
	Tablet		
378	Fluconazole 50mg/5ml Oral	For systemic candidiasis,	29-5-2000
	Suspension	mucosal candidiasis,	
		cryptocosis, prevention of	
		fungal infection in patients	
		with malignancy.	
379	Combination Vaccine DPT +	For active immunization of	1-6-2000
	Hi-b	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.	
380	Pantoprazole Sodium 40mg per	Deodenal ulcer, gastric ulcer,	7-6-2000
	vial i.v Injection	moderate and severe reflux	
		oesophagitis.	
381	Sodium Dichloro Isocyanurate	For chlorination of drinking	12-6-2000
	35mg/350mg/1.75g/3.5g	water.	
	Tablet		
382	r Human Erythropoeitin	For additional indication of	19-6-2000
	1000IU/ml, 2000IU/ml,	perisurgery	
	3000IU/ml, 4000IU/ml,		
	10000IU/ml Injection		

383	Rofecoxib 12.5mg/25mg	By RMP- for osteoarthritis,	26-6-2000
	Uncoated Tablet	acute pain, dysmenorrhoea	
		only.	
384	Irbesartan 75mg/150mg/300mg	By RMP- for the treatment of	26-6-2000
	Uncoated Tablet	mild to moderate hypertension	
		only.	
385	Cyclosporin 10mg Capsule	As additional strength.	27-6-2000
386	Rosiglitazone Maleate	By RMP- for treatment of	28-6-2000
	1mg/2mg/4mg/8mg Film	type-II diabetes mellitus as	
	Coated Tablet	mono therapy & adjunct to	
		diet.	
387	Methyl Hydroxy Propyl	By RMP- for temporary relief	5-7-2000
	Cellulose 0.3% Eye Drops	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.	
388	i)Granisetron Hcl 1mg/2mg	By RMP- for nausea vomiting	5-7-2000
	Film Coated Tablet	in cancer patients treated with	
	ii)Granisetron Hcl 1mg/ml	cytotoxic drugs.	
	Injection		
389	Rituximab 10mg/ml vial	By cancer specialist-for the	10-7-2000
	(Concentrate for solution for	treatment of patients with	
	infusion)	relapsed or chemo resistant	
		indolent B cell Non-Hodgkin's	
		lymphomas.	
390	Trastuzumab 440mg/vial	By cancer specialist-in	10-7-2000
	Powder Concentrate Infusion	metastatic breast cancer who	
		have tumours that over express	
		human epidermal growth factor	
		receptor-2 (HER2).	
391	Recombinant Human	For additional indication-	12-7-2000

	Erythropoietin (r Hu Epo)	anaemia associated with	
		cancer.	
392	Amphotericin B (USP) 5mg/ml	By RMP- for the treatment of	12-7-2000
	per 10ml/20ml Lipid Complex	invasive fungal infection in	
	Injection	patients who are refractory to	
		or intolerant of conventional	
		amphotericin-B therapy.	
393	Rosiglitazone 2mg/4mg/8mg	For additional indication of "in	14-7-2000
	Tablet	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".	
394	Sodium Valporate	For additional indications-	17-7-2000
	Tablet/Syrup	manic episodes associated with	
		bipolar disorders.	
395	Synthetic Salmon Calcitonin	By RMP- in post menopausal	18-7-2000
	50IU/100IU/200IU Nasal	osteoporosis, bone pain	
	Spray	associated with osteolysis	
		and/or osteopenia Paget's	
		disease.	
396	Moclobemide 150mg/300mg	By psychiatrist- major	28-7-2000
	Film Coated Tablet	depression & social phobia.	
397	Insulin Lispro Mixtures	Already approved for different	31-7-2000
	(rDNA) Injection	mixtures, diabetes mellitus.	
398	Candesartan Cilexetil	By RMP- for mild to moderate	31-8-2000
	4mg/8mg/16mg Tablet	essential hypertension only.	
399	Levonorgestrel 52mg Sterile	By RMP- contraception,	13-9-2000
	Intra Uterine System	menorrhagia & endometrial	
		hyperplasia during estrogen	
		replacement therapy in women.	
400	rDNA Hepatitis B Vaccine		15-9-2000

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

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

416	rHuman Erythropoeitin	For hospitals/institutions &	8-11-2000
	2000IU/4000IU per vial	prescription of cancer	
	Injection	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	By RMP- HIV infection when	15-11-2000
	25mg/50mg/100mg Chewable	anti-retroviral therapy is	
	Tablet	wanted.	
418	Fluticasone Propionate B.P	By RMP- for the prophylactic	27-11-2000
	0.5mg/2.0mg per 2ml Respule	management of severe chronic	
		bronchial asthma in patients	
		requiring high dose inhaled or	
		oral corticosteroid therapy.	
419	Liposomal Doxorubicin Hcl	Additional indication-for the	29-11-2000
	2mg/ml Pegylated Injection	treatment of metastatic	
		carcinoma of the ovary in	
		patients with diseases,	
		refractory to both paclitaxel	
		and platinum based	
		chemotherapy.	
420	Otilonium Bromide 40mg	By RMP- in treatment of	15-12-2000
	Tablet	irritable bowel syndrome,	
		painful spastic condition of	
10:		distal enteric tract.	
421	Pravastatin Sodium	By RMP- primary	20-12-2000
	10mg/20mg/40mg Uncoated	hypercholesterolemia type IIa,	

	Tablet	IIb and prevention of	
		cardiovascular events in adults	
		only.	
422	Somatropin (r human growth	By endorinologists- growth	20-12-2000
	hormone) 24IU/8mg	failure due to in adequate	
	, ,	secretion of normal	
		endogenous growth hormone.	
423	Beclomethasone Dipropionate	By RMP- for treatment of	21-12-2000
	50mcg/100mcg/250mcg	asthma.	
	Inhaler		
424	Recombinant Interferon Alpha-	For use in cancer-	27-12-2000
	2b	hospital/institution and against	
	3mIU/5mIU/10mIU/18mIU/	the prescription of specialists	
	25mIU Injection	only- for multiple myeloma,	
		AIDS related kaposis sarcoma,	
		malignant melanoma, hairy cell	
		leukemia, chronic	
		myelogenous leukemia,	
		laryngeal papillomathesis,	
		condylomata, acuminata,	
		superficial and nudulo	
		ulcerative basal cell carcinoma	
		chronic hepatitis-B and	
		hepatitis-C.	
425	Budesonide 200mcg Aerosol	For bronchial asthma	14-05-1992
	inhalation (Each metered		
	inhalation supplies Budesonide		
	200mcg)		
426	Budesonide 100mcg metered		29-05-1992
	actuation inhaler (Each		
	metered inhalation supplies		
	Budesonide 100mcg)		
427	Budesonide Respules		16-08-1995

0.25mg/ml or 0.5mg/ml (2m
single dose unit ampule
containing 0.25mg/ml o
0.5mg/ml suspension in a
suspension for nebulisation.

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.