

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 |

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| | 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 |

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| 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 |

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| | | 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 |

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| | 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 |

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| | 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 |

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| | (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 |

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| | 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 |

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| | | 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 |

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| | 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 |

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| | 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 |

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| | | 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 |

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| 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 |

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| | 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 |

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| 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 |

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| | | 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 |

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| 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 |

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| | 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 5ml 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 04-09-1995 |

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| 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 |

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| | 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 |

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| | 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 |

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| | | 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 |

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| | 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 |

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| 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 |

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| | 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 genococcal and non genococcal urethritis in males, uncomplicated UTI skin soft tissue infections, ENT infections. | 11-11-1996 |

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| 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 |

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| | | 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 |

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| | | 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 |

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| | | 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 |

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| | 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 |

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| | | 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 |

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| | 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.boulardii- 282.5mg Sachet ii)Lyophilized S.boulardii- 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 |

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| | | 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 |

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| | | 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 |

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| 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 |

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| | | 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 |

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| 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 |

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| | | 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 |

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| 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 |

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| | 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 |

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| | 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 |

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| | 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 |

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| 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 48mg | Osteoarthritis pain due to musculoskeletal disorder. | 16-03-2000 |
| 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 |

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| 375 | Cerivastatin Sodium 100mcg/200mcg/300mcg Tablet | By RMP- primary hypercholesterolemia type IIa, IIb resistant to diet. | 11-5-2000 |
| 376 | Roxithromycin 75mg Tablet | For paediatric use. | 15-5-2000 |
| 377 | Amoxicillin 3H2O 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 |

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| 383 | Rofecoxib 12.5mg/25mg Uncoated Tablet | By RMP- for osteoarthritis, acute pain, dysmenorrhoea only. | 26-6-2000 |
| 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 | For additional indication- | 12-7-2000 |

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| | Erythropoietin (r Hu Epo) | anaemia associated with 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 sulphonyl 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 | | 15-9-2000 |

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| | (10mcg) | | |
| 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 | 12-10-2000 |

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| | | containing chemotherapy 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 |

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| 416 | rHuman Erythropoietin 2000IU/4000IU per vial Injection | For hospitals/institutions & 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 autologous pre-donation program and peri-surgery patients without blood donation. | 8-11-2000 |
| 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 | By RMP- primary hypercholesterolemia type IIa, | 20-12-2000 |

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| | Tablet | Iib and prevention of 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 papillomatosis, condylomata, acuminata, superficial and nodulo ulcerative basal cell carcinoma chronic hepatitis-B and hepatitis-C. | 27-12-2000 |
| 425 | Budesonide 200mcg Aerosol inhalation (Each metered inhalation supplies Budesonide 200mcg) | For bronchial asthma | 14-05-1992 |
| 426 | Budesonide 100mcg metered actuation inhaler (Each metered inhalation supplies Budesonide 100mcg) | | 29-05-1992 |
| 427 | Budesonide Respules | | 16-08-1995 |

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