

Sr. No	Name of the firm	Name of the Drug	Date of Permission	Indication	Permission No.	Dosage Form & strength
1	Ethnor Limited	r-hu-EPO	24-8-1993	Anaemia due to chronic renal failure	Nil	each vial contains 2000 IU, 4000 IU, 10,000 IU
2	Roche Products (India) Pvt.Ltd	Granulocyte colony stimulating factor (Filgrastim) (Neupogen)	30-Sep-93	filgrastim is indicated to Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever · Reduce the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML) · Reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT) · Mobilize autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis · Reduce the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia · Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome)	Nil	

3	Organon India	FOLLITROPIN BETA (FSH-Recagon) Puregon	14-1-1996	for the treatment of female infertility in the following situations: -anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomiphene citrate -controlled ovarian hyperstimulation to induce the development of multiple follicle in medically assisted reproduction programme (eg in vitro fertilization/embryo transfer (IVF/ET) , gamete intra fallopian transfer (FIFT) and intracytoplasmic sperm injection (ICSI))	Nil	
4	Johnson & Johnson Ltd	R-Hu-EPO	13-6-1996	treatment of anaemia due to chronic renal failure and end stage renal diseases	nil	each vial contains 2000 Units, 4000 Units, 10,000 Units
5	Roche Products (India) Pvt.Ltd	Erythropoeitin	9-Sep-97	treatment of anaemia due to chronic renal failure and end stage renal diseases for treatment of symptomatic anaemia in adult patients, with non-myeloid malignancies receiving chemotherapy for prevention of anemia of prematurity in infants with birth weight of 750 gm to 1500 gm and gestational age of less than 34 weeks for increasing the yield of autologous blood from patients in a pre-donation program	Nil	
6	Eli Lilly and Company Pvt. Ltd	Somatropin	4-2-1998	Growth Failure due to inadequate secretion of normal endogenous growth hormone	Nil	
7	Serum Institute of India	Somatropin (Saizen)	17-2-1998	Growth Failure due to inadequate secretion of normal endogenous growth hormone	Nil	4 IU/10IU /Vial

8	Eli Lilly and Company Pvt. Ltd	Hu-Insulin	18-4-1998	Diabetes Mellitus.	Nil/ 12-28/94-DC	1) Hu-Insulin regular 40U/ml, 100U/ml, USP; 2) Hu-Insulin Ispohane insulin suspension (NPH), 40U/ml, 100U/ml; 3) Hu-Insulin Zinc Suspension (lente), 40U/ml, 100U/ml; 4) Hu-Insulin Zinc Suspension (Ultralente), 40U/ml, 100U/ml; 5) Hu Insulin 10/90 (neutral solution & Isophane suspension), 40U/ml, 100U/ml; 6) Hu Insulin 20/80 (neutral solution & Isophane suspension), 40U/ml, 100U/ml; 7) Hu Insulin 30/70 (neutral solution & Isophane suspension), 40U/ml, 100U/ml; 8) Hu Insulin 40/60 (neutral solution & Isophane suspension), 40U/ml, 100U/ml; 9) Hu Insulin 50/50 (neutral solution & Isophane suspension), 40U/ml, 100U/ml
9	Serum Institute of India	Follitropin alfa (r-hu-FSH)	21-7-1998	treatment of female infertility	Nil	75IU/150IU
10	Novartis India Pvt Ltd	Basiliximab Injection	26-5-1999	Prophylaxis of acute organ rejection in de novo renal transplantation and is to be used concomitantly with cyclosporin for microemulsion and corticosteroid based immune-suppression	Nil	each vial contains Basiliximab- 20 mg alongwith ampoule of 5 ml water for injection
11	Eli Lilly and Company Pvt. Ltd	Insulin Lispro Mixture	31-7-2000	Diabetes Mellitus	Nil/ 12-56/94-DC	100U/ml, 3ml cartridge, 100U/ml, 10ml vial; 100U/ml, 3ml cartridge
12	Fulford India Ltd	R-Hu-INF alfa 2b	27-12-2000	Multiple myeloma, AIDS related kaposi's 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	Nil	Each vial contains: 3MIU/5MIU/10MIU/ 18MIU/25MIU
13	Kee Pharma Ltd	Hu-INF alpha 2b	2-1-2001	treatment of multiple myeloma, kaposi's sarcoma in AIDS patients with malignant neoplasia,	nil	3,5,10 MIU/vial
14	Fulford India Ltd	peg-INF alfa 2b Powder for injection	13-7-2001	treatment of chronic Hep C	Nil	50, 80, 100, 120 & 150 mcg
15	Kee Pharma Ltd	r-hu-EPO	16-8-2001	Anaemia due to chronic renal failure and end stage renal disease	Nil	each lyophilized vial contains 2000 IU, 4000 IU, 10,000 IU

16	LG Chemical India Ltd	INF alpha 2a	22-10-2001	Treatment of multiple myeloma, kaposi's sarcoma, hairy cell renal cell chronic myelogenous leukemia	Nil	3, 6, 9, MIU/vial
17	Pharmacia India	Somatropin (Recombinant)	23-11-2001	Short stature due to inadequate or failed secretion of pituitary growth Hormone	Nil	36IU (12mg Powder)
18	Serum International Ltd	R-hu-INF beta-1a	18-1-2002	treatment of patients with relapsing/remitting multiple sclerosis	Nil	22mcg(6MIU/0.5ml)/44mcg (12MIU/0.5ml)
19	Aventis Pharma Ltd.	Insuman Rapid, Insuman Basal, Insuman 15/85, Insuman 25/75, Insuman 50/50	07-05-2002	Treatment of Type I and Type II Diabetes Mellitus	Not mentioned	Insuman Rapid(5 ml vial and 3 ml cartridge of strength 100 IU/ml, 10 ml vial of strength 40 IU/ml), Insuman Basal(5 ml vial and 3 ml cartridge of strength 100 IU/ml, 10 ml vial of strength 40 IU/ml), Insuman 15/85 (5 ml vial and 3 ml cartridge of strength 100 IU/ml, 10 ml vial of strength 40 IU/ml), Insuman 25/75 (5 ml vial and 3 ml cartridge of strength 100 IU/ml, 10 ml vial of strength 40 IU/ml), Insuman 50/50 (5 ml vial and 3 ml cartridge of strength 100 IU/ml, 10 ml vial of strength 40 IU/ml)
20	Glenmark laboratories Pvt Ltd	INF alpha 2b	15-7-2002	multiple myeloma, kaposi's sarcoma in AIDS patients with malignant neoplasia	Import-82/02	3,5,10 MIU/vial
21	L.G.Chemicals	R-Hu-Growth Hormone (somatropin)	27-8-2002	Long-term treatment of growth failure associated with chronic renal insufficiency up to the time of renal transplant and patients suffered from Turner's syndrome	Nil	4IU/vial
22	Wyeth Lederle Ltd	Gemtuzumab Ozogemycin (Lyophilized Powder)	12-9-2002	treatment of acute myeloid leukemia	Nil	5mg/vial for IV use
23	Roche Products (India) Pvt.Ltd	Rituximab	8-Oct-02	Treatment of patients with relapse or chemo resistant indolent B cell	Nil	10mg/ml/vial
24	Roche Products (India) Pvt.Ltd	Daclizumab	11-Oct-02	the prophylaxis of acute organ rejection in patients receiving renal transplants	Nil	25mg in 5ml of solution for infusion
25	Roche Products (India) Pvt.Ltd	Trastuzumab	11-Oct-02	treatment of patients with metastatic cancer who have tumors that overexpress human epidermal growth factor	Nil	440mg/vial
26	Eli Lilly and Company Pvt. Ltd	Teriparatide (r-Hu-Parathyroid Hormone)	9-1-2003	For the treatment of patients with severe Osteoporosis	IMP-187	each Pre-filled Pen contains: 750 mcg/3 ml

27	Novo Nordisk India Pvt Ltd	r-hu-coagulation factor VIIa	14-1-2003	Treatment of bleeding episodes and prevention of excessive bleeding associated with surgery in patients with inherited hemophilia to coagulation factors VII or IX	Nil	60KIU/120KIU/240KIU/vial
28	Roche Products (India) Pvt.Ltd	Interferon alpha 2a (Pegylated)	13-Mar-03	treatment of multiple myeloma, kaposi's sarcoma in AIDS patients with malignant neoplasia, chronic active Hepatitis B & C.	Nil	0.5ml pre-filled syringe or 1ml vial contains 135mcg/ 180mcg respectively
29	Torrent Pharmaceuticals Ltd.	Insulin Crystals (Bulk)	17-03-2003		482	-
30	Novo Nordisk India Pvt Ltd	Insulin aspart Biphasic (Recombinant DNA)	2-5-2003	Treatment of type -I & II Diabetes Mellitus	12-86/99-DC	100 units/ml in the ratio of 30:70
31	Shreya Life Sciences	Somatropin	11-3-2004	Long-term treatment of growth failure associated with chronic renal insufficiency up to the time of renal transplant and patients suffered from Turner's syndrome	IMP-1259/04	4IU/12IU/18IU/vial
32	Serum Institute of India	r-hu-chorionic gonado tropin hormone (Chori onogonadotropin alfa)	20-5-2004	treatment of women superovulation prior to assisted reproductive techniques	Import-1432/04	250mcg/vial
33	Glenmark laboratories Pvt Ltd	R-Hu-GCSF Injection	13-10-2004	For decreasing severity of chemotherapy induced neutropenia. Cancer patients receiving Myelosuppressive chemotherapy	Import-1794/04	75mcg/0.30ml, 150mcgmcg/0.60ml & 300mcg/0.90ml
34	Cadila Healthcare Ltd	Recombinant Interferon β 1b Injection	14-10-2004	Relapsing-remitting and secondary progressive multiple sclerosis	Import-1793/04	Recombinant Interferon β 1b Injection---0.25mg
35	Roche Products (India) Pvt.Ltd	Bevacizumab Injection	17-Jan-05	1. For the treatment of Metastatic Colorectal Cancer (mCRC) 2. For the treatment of First-Line Non-Squamous Non-Small Cell Lung Cancer (NSCLC) 3. For the treatment of Recurrent Glioblastoma (GBM) 4. For the treatment of Metastatic Renal Cell Carcinoma (mRCC) 5. For the treatment of Persistent, Recurrent, or Metastatic Cervical Cancer 6. For the treatment of Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer 7. For the treatment of Metastatic Breast Cancer	Import-1992/04	100mg/4ml

36	Nicholas Piramal India Ltd/ Biogen Idec	INF beta-1a (avonex)	2-2-2005	treatment of ambulatory patients with replasing multiple sclerosis	Import-2038/04	Each pre-filled syringe 300mcg/ 0.5ml
37	Novo Nordisk India Pvt Ltd	Hu-somatropin hormone	29-3-2005	treatment of growth hormone deficiency	import-3056/05	5, 10, 15mg/1.5ml
38	Novo Nordisk India Pvt Ltd	R-Hu-Growth Hormone (somatropin)	29-3-2005	Long-term treatment of growth failure associated with chronic renal insufficiency up to the time of renal transplant and patients suffered from Turner's syndrome	Import-3056/05	1.5ml PFS 5,10,15mg
39	Novo Nordisk India Pvt Ltd	R-Insulin- Determir Injection	15-7-2005	for the treatment of patinets with diabetes Mellitus	Import-5092/05	100 units/ml
40	Boehringer Ingelheim Pvt Ltd	Alteplase	14-09-2005	For fibrionlytic therapy in acute thrombolytic coronary artery occlusion, acute MI, acute ischaemic stroke, acute massive pulmonary embolism	Nil	Recombinant Human Tissue Type plasminogen activator Injection, 1 vial contains 20 mg or 50 mg
41	Merck Specialities Pvt Ltd	Cetuximab	2-2-2006	Treatment of patients with Epidermal growth factor	Import-6370/06	100mg in 50ml vial
42	Biocon Limited	Nimotuzumab	28-Jun-06	Treatment of Head & Neck Cancer	IMP-6669/06	50mg/ml Vial
43	VHB Life Sciences	Erythropoietin	38932	For treatment of anemia and chronic renal failure	IMP-771/06	InjectionEach vial contains EPO ---1000 /2000/3000/4000/5000/10000/20000 and 40000 IU
44	Biocon Limited	Erythropoietin	31-Aug-06	For the treatment of patinets with anaemia due to chronic renal failure, either on dialysis or non-dialysis	IMP-6885/06	Injection.....Each 1 ml vial contains.....2000 IU, 4000 IU, 10,000 IU
45	Roche Products (India) Pvt.Ltd	Granulocyte colony stimulating factor (Peglyated) - Pegfilgrastim	12-Oct-06	For reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for maliganancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)	Import-6941/06	Each PFS (0.6 ML) conatins 6ML Peg-GCSF
46	Hindustan Bio sciences Ltd	r-hu-EPO Injection	31-Oct-06	Anaemia due to chronic renal failure	Import-6982/06	each vial of 1ml contains 2000/3000/4000 IU
47	Taksal Pharma Pvt. Ltd.	Granulocyte Colony Stimulating Factor	12-Dec-06	For reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for maliganancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)	IMP-7067/06	Each PFS (0.6 ML) conatins 6ML Peg-GCSF
48	Boehringer Ingelheim Pvt Ltd	Tenecteplase (TNK-TPA)	6-Feb-07	For thrombolytic treatment of acute Myocardial Infraction (AMI)	Import-7146/07	each vial contains 40 mg/50mg

49	Serum institute of India	r-human-Efalizumab injection	25-Apr-07	Treatment of adult patients with moderate to severe plaque psoriasis	Import-7392/07	100mg/ml
50	LG Life sciences India	R-Follicle stimulating hormone injection	3-5-2007	treatment of female infertility	Import-7398/07	each vial contains 75IU/150IU
51	Biocon Limited	Erythropoietin alpha (Bulk new drug substance)	31-Jul-07	Not Applicable	IMP-7792/07	> 4000 IU bulk
52	Novartis India Pvt Ltd	Ranibizumab	28-9-2007	For improvement and maintenance of visual acuity and function and for reduction of vascular leakage and retinal oedema, in patients with neovascular age related macular degeneration (AMD)	Import-6932/06	each 1ml contains 10mg
53	Biocon Limited	Paclitaxel (Protein-bound particles)	11-Oct-07	Treatment of breast cancer	IMP-7978/07	100mg/20ml
54	Generex Biotechnology	Hu-Insulin Aerosol Suspension from M/s Farmacid S.A. Quito Ecuador)	15-Oct-07	For the treatment of insulin dependent diabetes mellitus	Import-8038/07	Suspension for buccal administration Hu-Insulin 14.44 gm
55	Aventis Pharma Ltd.	r-Hu-Insulin	17-10-2007	Treatment of Diabetes Mellitus in adults patients only	IMP-8021/07	Each ml contains 3.5mg (100IU) Each Cartridge, pre-filled pen contains- 3ml equiv. to 300 IU insulin Glulisine
56	Taksal Pharma Pvt. Ltd.	Methoxy Polyethylene Glycol-Erythropoietin beta	23-Nov-07	Treatment of anemia associated with chronic kidney disease	IMP-8199/07	Injection.....Each 1ml vial contains 50µ/100µ/ 200µ/300µ/400µ & 600µ.....Each pre-filled syringe (0.3ml) contains: 50µ/75µ/ 100µ/150µ/200µ/250µ/400µ/600µ & 800µ
57	Roche Products (India) Pvt.Ltd	Methoxy Polyethylene Glycol-EPO beta	23-Nov-07	treatment of anaemia associated with chronic kidney disease	Import-8198/07	each 1ml vial contains 50µ/100µ/ 200µ/300µ/400µ & 600µ, each pre-filled syringe (0.3ml) contains: 50µ /75µ / 100µ / 150µ /200µ /250µ /400µ /600µ & 800µ
58	Sudershan Biotech Ltd.	Granulocyte Colony Stimulating Factor	17-1-2008	Treatment of neutrophilic granulocytopenia reduced by chemotherapy of cancer and bone marrow transplantation	Import-42/08	Injection..... 75/150/300mcg/pre-filled syringe
59	Lupin limited	Abciximab	23-Jan-08	For the treatment of unstable angina and prevention of ischemic cardiac complications in patients undergoing Percutaneous Coronary Intervention(PTCA).	IMP-89/2008	Injection..... Each 1ml of solution contains abciximab 2mg

60	Reliance Biopharmaceuticals	r-Hu-EPO	30-1-2008	For the treatment of anemia due to chronic renal failure patients.	Import-177/08	Each pre-filled syringe: r-Hu-EPO-10,000 IU/ml
61	Reliance Biopharmaceuticals	r-hu-EPO (Bulk)	31-1-2008		Import-186/07	
62	APC Pharmaceuticals and Chemicals	Somatropin	28-Mar-08	Long-term treatment of growth failure associated with chronic renal insufficiency up to the time of renal transplant and patients suffered from Turner's syndrome	Import-1555/04	InjectionEach vial contains Somatropin 4IU(1.6mg) and 10IU(4.0 mg)
63	Shreya Life Sciences	R-Hu-Growth Hormone	5-9-2008	Long-term treatment of children who have growth failure due to endogenous growth hormone and for treatment of short stature in children with Turner's syndrome confirmed by chromosomal analysis.	Import-966/08	Powder for injection and Solution for injection.....Each vial after reconstitution contains ..r-Growth hormone- 5.8mg/vial,Each cartridge of 1.5 ml contains 5mg (15 IU) and 10mg (30 IU) solution for injection
64	Taksal Pharma Pvt. Ltd.	Tocilizumab	7-1-2009	For disease which do not show sufficient response to the existing therapies - eg;- Rheumatoid Arthritis (including inhibition of progression of structural joint damage), polyarticular-course juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis. Improvement of various symptoms (e.g- generalized fatigue) and laboratory findings (increased C-reactive protein, fibrinogen, and erythrocytic sedimentation rate decreased haemoglobin and albumin) associated with Castleman's disease.	Import-1404/08	Injection.....Each vial of 4, 10, 20 ml contains Tocilizumab 20mg/mL
65	Baxalta Bioscience India Pvt Ltd (Earlier Bayer)	Anti Haemophilic factor VIII	1-4-2009	for supplementing blood coagulation factor VIII and suppresses bleeding tendency in congenital blood coagulation Factor VIII deficient patients (Haemophilia A)	IMP-341/09	Lyophilized powder for IV injection.....250 IU OR 500 IU OR 1000 IU after reconstitution with 10 ml SWFI
66	Merck Specialities Pvt Ltd	Follitropin alfa (r-hu-FSH)	1-4-2009	treatment of female infertility	Import-339/09	300IU/0.5ml, 450IU/0.75ml, 900IU/1.5ml
67	Merck Specialities Pvt Ltd	r-hu-chorionic gonadotropin hormone (ovitrelle)	1-4-2009	Indicated in the treatment of women undergoing superovulation prior to assisted reproductive techniques such as IVF & anovulatory or oligo-ovulatory patients after stimulation of follicular growth	Import-338/09	solution for injection 250 mcg
68	Merck Specialities Pvt Ltd	Hu-somatropin hormone	22-4-2009	Growth deficiency associated with proven insufficient secretion of endogenous growth hormone	Import-385/09	1.33mg and 3.33mg

69	Merck Specialiteis Pvt Ltd	r-DNA Hu-Somatropin Hormone	22-4-2009	Growth deficiency associated with proven insufficient secretion of endogenous growth hormone	Import-384/09	1.33mg/3.33mg
70	Merck	R-hu-INF beta-1a (Rebif)	22-4-2009	treatment of relapsing multiple sclerosis	Imp-383/09	0.5ml pre-filled syringe
71	Novo Nordisk	Biphasic Isophane Insulin Injection	14-5-2009	for the treatment of patients with diabetic Mellitus	Import-464	each 3ml cartridges contains 100 IU/ml
72	Novo Nordisk India Pvt Ltd	Insulin Aspart	14-5-2009	for the treatment of patients with diabetic Mellitus	Import-466	each 3ml cartridges contains 100 IU/ml
73	Novo Nordisk India Pvt Ltd	Isophane Insulin Injection	14-5-2009	for the treatment of patients with diabetic Mellitus	Import-465	each 3ml cartridges contains 100 IU/ml
74	Novo Nordisk India Pvt Ltd	Soluble Insulin Injection I.P.	14-5-2009	for the treatment of patients with diabetic Mellitus	Import-463	each 3ml cartridges contains 100 IU/ml
75	Eli Lilly and Company Pvt. Ltd	Insulin lispro	20-5-2009	Treatment of patients with diabetic Mellitus	Import-483/09	100 IU/ml Pen solution for injection
76	Claris	GCSF	29-5-2009	Increase neutrophilic count after bonemarrow transplantation, neutro-philic granulocytopenia reduced by chemotherpay of cancers inducing maligna-nt lymphoma, embryonic cell tumor, neuroblastoma.	Import-520/09	Each PFS contains 300mcg/0.9ml
77	Gufic lifesciences	GCSF	29-5-2009	Increase neutrophilic count after bonemarrow transplantation, neutro-philic granulocytopenia reduced by chemotherpay of cancers inducing maligna-nt lymphoma, embryonic cell tumor, neuroblastoma.	Import-531/09	Each PFS contains 300mcg/0.9ml
78	KSR Pharmacy	GCSF	10-7-2009	Increase neutrophilic count after bonemarrow transplantation, neutro-philic granulocytopenia reduced by chemotherpay of cancers inducing maligna-nt lymphoma, embryonic cell tumor, neuroblastoma.	Import-613/09	Each PFS contains 300mcg/0.9ml
79	Chandra Bhagat pharma Ltd	R-Hu-GCSF Injection	21-7-2009	Increase of neutrophilic count after bonemarrow transplantation, neutro-philic granulocytopenia reduced by chemotherpay of cancers inducing maligna-nt lymphoma, embryonic cell tumor, neuroblastoma.	MF-643/09	Each PFS contains 300mcg/0.9ml

80	VHB Life Sciences	Granulocyte Colony Stimulating Factor	4-8-2009	(a) Enhance and increase the neutrophilic granulocyte count after bone marrow transplantation. (b) neutrophilic granulocytopenia reduced by chemotherapy of cancers inducing malignant lymphoma, embryonic cell tumor (spermatic tumor, ovary tumor), neuroblastoma and so on. (c) Neutrophilic granulocytopenia contaminant with myelodysplastic syndrome. (d) Neutrophilic granulocytopenia contaminant with aplastic anemia. (e) Congenital and spontaneous neutrophilic granulocytopenia	IMP-661/09	Pre-filled syringe injection Each PFS contains 300mcg/0.9ml
81	USV Ltd	Granulocyte Colony Stimulating Factor	2-9-2009	(a) Increase the neutrophilic granulocyte count after bone marrow transplantation. (b) neutrophilic granulocytopenia reduced by chemotherapy of cancers inducing malignant lymphoma, embryonic cell tumor (spermatic tumor, ovary tumor), neuroblastoma and so on. (c) Neutrophilic granulocytopenia contaminant with myelodysplastic syndrome. (d) Neutrophilic granulocytopenia contaminant with aplastic anemia. (e) Congenital and spontaneous neutrophilic granulocytopenia	IMP-730/09	75mcg/0.30ml, 150mcgmcg/0.60ml & 300mcg/0.90ml
82	Trigenesis Life Sciences	Granulocyte Colony Stimulating Factor	8-9-2009	increase the neutrophilic granulocyte count after bone marrow transplantation. (b) neutrophilic granulocytopenia reduced by chemotherapy of cancers inducing malignant lymphoma, embryonic cell tumor (spermatic tumor, ovary tumor), neuroblastoma and so on. (c) Neutrophilic granulocytopenia contaminant with myelodysplastic syndrome. (d) Neutrophilic granulocytopenia contaminant with aplastic anemia. (e) Congenital and spontaneous neutrophilic granulocytopenia	MF-753/09	Pre-filled syringe injection.....75mcg/0.30ml, 150mcgmcg/0.60ml & 300mcg/0.90ml
83	USV Ltd	Interferon alpha 2b	25-9-2009	Chronic Hepatitis B & C	IMP-801/09	Vial (Lyophilized) for injection..... Each vial contains 3, 5 MIU/ml of human recombinant alpha 2b interferon

84	Sanofi-Synthelabo (India) Pvt. Ltd	Rasburicase	22-Dec-09	Treatment and prophylaxis of acute hyperuricaemia, in order to prevent acute renal failure in patients with haematological malignancy with a tumor burden and at a risk of a rapid tumor lysis or shrinkage at initiation of chemotherapy	Import-1043/09	1.5mg/ml, 7.5mg/ml powder and solvent for solution for infusion
85	Novo Nordisk India Pvt Ltd	Liraglutide	8-Feb-10	Treatment of type-II Diabetes Mellitus	Import-139/2010	Solution for injection in prefilled pen contains 18 mg of Liraglutide/ 3 mL
86	VHB MedisciencesLtd	r-hu-GCSF-injection (Filgrastim)	4-Mar-10	Increase of neutrophilic count after bone marrow transplantation, neutro-philic granulocytopenia reduced by chemotherpay of cancers inducing malignant lymphoma, embryonic cell tumor, neuroblastoma.	MF-189/2010	Prefilled syringe contains 300 mcg per 0.9 mL
87	FerringPharmaceut icals	r-Hu-Growth Hormone (Somatropin)	4-Apr-10	Long term treatment of children who have growth failure due to inadequate secretion of growth hormone and for the long-term treatment of growth retardation due to Turner's syndrome	Import-450/2010	Lyophilized powder for injection in vials contains somatropin 4 mg
88	Bioviz Technologies Pvt Ltd	Erythropoetin (r-Hu-EPO)	14-Jun-10	For the treatment of anemia due to chronic renal failure.	Import-532/2010	Injection in 1 mL of prefilled syringe contains r-Hu-EPO 2000IU/mL or 4000IU/mL
89	Bioviz Technologies Pvt Ltd	r-Hu-EPO	14-6-2010	For the treatment of anemia due to chronic renal failure.	Import-532/10	Each pre-filled syringe of 1ml contains: r-Hu-EPO-2,000 /4,000 IU
90	Bioviz Technologies Pvt Ltd	r-hu-GCSF-injection (Filgrastim)	14-Jun-10	For decreasing severity of chemotherapy induced neutropenia. Cancer patients receiving Myelosuppresice chemotherapy	Import-533/2010	Injection in 1 mL of prefilled syringe contains r-Hu-EPO 2000IU/mL or 4000IU/mL
91	Bioviz Technologies Pvt Ltd	r-hu-GCSF-injection	14-6-2010	For decreasing severity of chemotherapy induced neutropenia. Cancer patients receiving Myelosuppresice chemotherapy	Import-533/10	Each PFS contains: r-Hu- GCSF- 75mcg/0.3ml, 150mcg/0.6ml and 300mcg/0.9ml
92	SciGen Biopharma Pvt Ltd	Somatropin	18-6-2010	Long-term treatment of children who have growth failure associated due to endogenous growth hormone and for treatment of short stature in children with Turner's syndrome confirmed by chromosomal analysis	Import-559/10	Powder for injection and Solution for injection.....Each vial after reconstitution contains 5.8 mg (17.41 IU);solution for injection. Each cartridge of 1.5ml contains 5mg (15 IU) and 10 mg (30 IU)
93	G.C.Chemie	r-hu-GCSF-injection (Filgrastim)	23-Jun-10	Increase neutrophilic count after bonemarrow transplantation, neutrophilic granulocytopenia reduced by chemotherpay of cancers inducing malignant lymphoma, embryonic cell tumor, neuroblastoma.	IMP-572/2010	solution for injection in 1 mL of prfilled syringe contains r-Hu-GCSF 300 mcg

94	R.K. Medicare	r-hu-GCSF-injection (Filgrastim)	9-Sep-10	Increase neutrophilic count after bonemarrow transplantation, neutro-philicgranulocytopenia reduced by chemotherpay of cancers inducing malignant lymphoma, embryonic cell tumor, neuroblastoma.	IMP-783/2010	solution for injection in prfilled syringe contains r-Hu-GCSF 300 mcg/0.9 mL
95	R.K. Medicare	r-hu-GCSF-injection	9-9-2010	Increase neutrophilic count after bonemarrow transplantation, neutro-philic granulocytopenia reduced by chemotherpay of cancers inducing malignant lymphoma, embryonic cell tumor, neuroblastoma.	IMP-783/10	Solution for injection 300mcg/0.9ml
96	Bioviz Technologies Pvt Ltd	r-hu-EPO (Bulk-Ready to fill)	22-12-2010		Bulk-531/10	2000 IU/ml and 4000 IU/ml
97	Novartis India Pvt Ltd	Canakinumab	5-1-2011	For the treatment of CAPS in adults, CAPS include: 1. Familial cold autoinflammatory syndrome/familial cold urticaria. 2. Muckle-wells syndrome, 3. Neonatal-onset multisystem inflammatory disease/chronic infantile neurological cutaneous articular syndrome (CINCA)	MF-1124/10	One vial contains 150 mg of canakinumab each ml of solution
98	KSR Pharmacy	Erythropoetin (r-Hu-EPO)	28-Jan-11	For the treatment of anemia due to chronic renal failure	IMP-04/2011	solution for injection in 1 mL of prefilled syringe contains r-Hu-EPO 2000IU/mL or 4000IU/mL
99	KSR Pharmacy	r-Hu-EPO	28-1-2011	For the treatment of anemia due to chronic renal failure	IMP-04/2011	Solution for injection in PFS Syringes: Each 1ml PFS contains: 2000Iu/4000IU
100	Lupin limited	Erythropoetin	17-Aug-11	Anemia due to renal inadequacy	IMP-35/2011	Injection (IV/SC).....Each prefilled syringe contains of 1 mL contains r-Hu-EPO 2000IU/mL, 3000IU/mL or 4000IU/mL
101	L.G.Lifesciences	Insulin Glargine	20-Dec-11	For once daily subcutaneous administration for treatment of adult patients with Type I Diabetes Mellitus or Type II Diabetes Mellitus who required basal (long acting) insulin for the control of Hyperglycemia	IMP-636/2011	Injection for SC administration in vial or Cartridge contains Insulin Glargine 100IU/mL
102	Vita pharma	Erythropoetin (r-Hu-EPO)	24-Apr-12	Anemia due to renal inadequacy	IMP-653/2011	Solution for IV/SC injection in 1 mL of prefilled syringe contains r-Hu-EPO 2000IU/mL, 3000IU/mL or 4000IU/mL

103	Bristol Myers Squibb India Pvt. Ltd	Belatacept	13-Jun-12	belatacept in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection and preservation of renal function in adults receiving a renal transplant . It is recommended to add an interleukin -2 receptor antagonist for induction therapy to this belatacept- based regimen.	IMP-160/2012	Lyophilized powder fir IV infusion in vial contains Belatacept 250 mg
104	Taksal Pharma Pvt. Ltd.	Trastuzumab	26-Jul-12	• It is indicated for treatment of patients with metastatic breast cancer who have tumors that overexpress human epidermal growth factor receptor 2 (HER2)- (For 440mg only) • Treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable) - (For 440mg only) • In combination with an aromatase inhibitor for the treatment of patients with HER2-positive and hormone receptor-positive metastatic breast cancer.- (For 440mg only) • For adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel b. With docetaxel and carboplatin - (For both 440mg & 150mg) • In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease.	IMP-194/2012	Lyophilized powder for solution for infusion in single dose and multidose vial. Strength: 1. Each multidose vial contains Trastuzumab 440 mg 2. Each singledose vial contains Trastuzumab 150 mg

105	M/ s Taksal pharma pvt. Ltd.	Trastuzumab	26/07/12	• It is indicated for treatment of patients with metastatic breast cancer who have tumors that overexpress human epidermal growth factor receptor 2 (HER2)- (For 440mg only) • Treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable) - (For 440mg only) • In combination with an aromatase inhibitor for the treatment of patients with HER2-positive and hormone receptor-positive metastatic breast cancer.- (For 440mg only) • For adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer a. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel b. With docetaxel and carboplatin -(For both 440mg & 150mg) • In combination with capecitabine or 5-fluorouracil and cisplatin for the treatment of patients with HER2 positive metastatic adenocarcinoma of the stomach or gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease. Trastuzumab should only be used in patients with h metastatic gastric cancer whose tumours have HER2 2 overexpression as defined by IHC2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.- (For both 440mg & 150mg)	IMP-194/2012	lyophilized power for solution infusion
106	Taksal Pharma Pvt. Ltd.	Interferon alfa-2a (Pegylated)	21-Aug-12	• It is indicated for treatment of chronic active Hepatitis B and C. • The combination of Pegasys and ribavirin is indicated in native patients and patients who have failed previous treatment with interferon alpha (Pegylated or non-pegylated) alone or in combination therapy with ribavirin. • For treatment of patients having chronic Hep-C co infected with clinically stable HIV.	IMP-223/2012	Solution for injection in 0.5 mL prefilled syringe or 1.0 mL vial contains Peg-INF alfa 2a 135mcg/180mcg

107	Taksal Pharma Pvt. Ltd.	Rituximab	21-Aug-12	• For treatment of patients with relapsed or chemo resistant Indolent B cell Non-Hodgkin's Lymphoma. • The treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with CVP chemotherapy. • Maintenance therapy for the treatment of follicular lymphoma patients responding to induction therapy. • The treatment of patients with CD20 positive diffuse large B cell non- Hodgkin's lymphoma in combination with CHOP chemotherapy • For the treatment of adult patients with active rheumatoid arthritis who have had an inadequate response or intolerance to one or more Tumour necrosis factor (TNF) inhibitor therapies. • MabThera has been shown to reduce rate of progression of Joint damage as measured by X-ray and to improve physical function when given in combination with Methotrexate. • MabThera in combination with chemotherapy is indicated for the treatment of patients with previously untreated & relapsed/ refractory chronic lymphocytic leukaemia. Only limited data are available on efficacy and safety for previously treated with monoclonal antibodies including Mabthera or patients refractory to previous MabThera plus chemotherapy. • MabThera in combination with glucocorticoids is indicated for the treatment of adult patients with Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)	IMP-222/2012	Concentrate for solution for injection in vial..... Each 10 mL vial contains Rituximab 100 mg and Each 50 mL vial contains Rituximab 500 mg
-----	-------------------------	-----------	-----------	---	--------------	---

108	Cipla Limited	Etanercept	8-Oct-12	It is used as alone or in combination with Methotrexate to treat active rheumatoid arthritis refractory to DMARDs including Methotrexate. Severe, active and rheumatoid arthritis in adults not previously treated with Methotrexate. active polyarticular course juvenile chronic arthritis refractory to methotrexate. Active and progressive Psoriatic arthritis refractory to DMARDs. Severe active ankylosing spondylitis refractory to conventional therapy Additional indication approved dated 03.Feb. 2014.....for Plaque Psoriasis.....Etanercept 25 mg is indicated for treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidate for systemic therapy or phytotherapy.....Etanercept 25 mg is indicated for treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by or are intolerant to other systemic therapies or phototherapies.	IMP-287/2012	lyophilized powder for solution for SC injections in vials in vials contains Etanercept 25 mg
109	Biocon Limited	Nimotuzumab (Bulk new drug substance)	27-Feb-13		Bulk-32/2013	Not Applicable
110	Biocon Limited	Erythropoietin alpha (Bulk new drug substance)	27.02.2013		Bulk-33/2013	2000 IU, 4000 IU and 10000 IU bulk
111	Sanofi-Synthelabo (India) Pvt. Ltd	Human insulin (Bulk new drug substance)	8-Mar-13	Diabetes Mellitus	Bulk-44/2013	Not Applicable

112	Johnson and Johnson Pvt Ltd	Infliximab	12-Mar-13	Indications: 1. The treatment of moderate to severely active Crohn's disease for the reduction of signs & symptoms in patients who have an inadequate response to conventional therapies. 2. Reduction in signs & symptoms of rheumatoid arthritis in patients who have had an inadequate response to methotrexate 3. Infliximab is a disease controlling anti-rheumatic therapy indicated for : - For the reduction of signs & symptoms - Prevention of structural joint damage - Improvement in physical functions in patients with active disease despite treatment with methotrexate 4. Ankylosing spondylitis in patients who have severe axial symptoms, elevated serological markers of inflammatory activity & who have responded inadequately to conventional therapy. 5. Reducing signs & symptoms & maintaining clinical remission in patients with moderately to severely active Crohn's disease. 6. For reducing signs & symptoms & including & maintaining clinical remission in patients with moderately to severely active Crohn's disease who have had an adequate response to conventional therapy & for reducing the number of draining enterocutaneous&rectovaginal fistulas & maintaining fistula closure in patients with fistulizing Crohn's disease 7. Use in early rheumatoid arthritis in patients with severe, active & progressive disease not previously treated with methotrexate or other DMARDs. 8. For the treatment of moderate to severe plaque psoriasis in adults who failed to respond to or who have a contraindications to or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA 9. For the treatment of Ulcerative Colitis 10. For the treatment of active & progressive psoriatic arthritis in adult when the response to previous disease modifying antirheumatic drug therapy has been inadequate & it should be administered in combination with methotrexate or alone in patients who show intolerance to methotrexate or for whom methotrexate is contraindicated. 11. For the reduction of signs & symptoms & induction & maintenance of clinical remission in adult & pediatric patients with moderately to severely active Crohn's disease who have inadequate response to conventional therapy. 12. Treatment of severe active Crohn's	IMP- 50/2013	Powder for concentrate for solution for infusion in vial contains 100 mg/10mL
-----	-----------------------------	------------	-----------	---	--------------	---

113	Roche Products (India) Pvt.Ltd	Bevacizumab Bulk	26-Apr-13		BULK-31/2013	Concentration: 25.0mg/ml Bevacizumab, 51mM sodium phosphate, pH 6.2, 0.04% Polysorbate 20, 60mg/ml, α α- trehalose dehydrate
114	Novo Nordisk India Pvt Ltd	Insulin degludec	05-Jul-13	Treatment of Diabetes Mellitus in Adults	IMP-134/2013	Solution for Subcutaneous injection.....Composition: 1ml of the solution contains: Insulin degludec.....100 units/200 units Presentation: Pre-filled Pen (FlexTouch™) / Cartridge (Penfill®) Fill Volume: 3.0 ml
115	Roche Products (India) Pvt.Ltd	Trastuzumab (Bulk drug)	02.08.2013		Bulk-141/2013	
116	LG Life sciencesIndia	Sustained release recombinant human growth hormone (somatropin)	20-Dec-13	It is indicated for the long-term treatment of children who have growth failure due to an inadequate secretion of normal endogenous growth hormone.	IMP-289/2013	Lyophilized powder for injection along with solvent for resuspension in vial contains somatropin 24 mg
117	Roche Products (India) Pvt.Ltd	Rituximab (Bulk drug)	2-Jan-14		BULK-262/2013	Concentration: 55 mg/mL
118	Roche Products (India) Pvt.Ltd	Rituximab (bulk new substance)	2-Jan-14		BULK-262/2013	55mg/ml
119	Shantha	human insulin-Bulk	06-Feb-14		Bulk-33/2014	
120	Johnson and Johnson Pvt Ltd	Golimumab	14-Feb-14	Rheumatoid arthritis (RA): Golimumab by subcutaneous administration, in combination with methotrexate (MTX), is indicated for: • Reducing signs and symptoms • Inducing major clinical response • Inhibiting the progression of structural damage. • Improving physical function.	IMP-279/2013	Each single use pre-filled syringe contains Golimumab.....50mg/0.5ml Presentations: UltraSafe / SmartJect

121	Alcon Laboratories (India) Pvt. Ltd.	Ranibizumab	17-07-2014	(1). For improvement and maintenance of visual acuity and function and for reduction of vascular leakage and retinal oedema, in patients with neovascular age related macular degeneration (AMD) (2). Treatment of visual impairment due to diabetic macular edema (DME) (3). Treatment of macular edema following Retinal vein occlusion (RVO) (4). Treatment of visual impairment due to choroidal NeoVascularization (CNV) secondary to Pathogenic Myopia (PM)	IMP-144/2014	Intravitreal injection in solution.....Each vial contains: Ranibizumab..... 2.3 mg in 0.23 ml solution Strength: 10 mg/ml Intravitreal injection
122	Novo Nordisk India Pvt Ltd	Insulin degludec/ Insulin Aspart	22-Jul-14	Treatment of Diabetes Mellitus in Adults	IMP-157/2014	Solution for SC injection in prefilled pen or cartridge (3 mL) contains 100 units of insulin degludec and insulin aspart (70 % soluble insulin degludec and 30 % soluble insulin as part)
123	Pfizer products India Pvt. Ltd	Etanercept (Enbrel)	27-Oct-14	• Reduction in signs and symptoms of moderately to severely active rheumatoid arthritis in patients who have had an inadequate response to one or more disease modifying anti-rheumatic drugs. • Moderately to severely active early rheumatoid arthritis and juvenile rheumatoid arthritis. • Treatment of alkalizing spondylitis in adults who have had inadequate therapy response to conventional therapy. • For reduction in signs and symptoms of active arthritis in patients with psoriatic arthritis. • Treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or photo therapy. • Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or photo therapies.	IMP-228/2014	Solution for SC injection in Prefilled syringes (25 mg) & pre filled pen (25mg/50 mg) of Etanercept in 1 mL
124	Sanofi-Synthelabo (India) Pvt. Ltd	Aflibercept	16-Dec-14	in combination with irinotecan-fluoropyrimidine based chemotherapy is indicated for patients with metastatic colorectal cancer (MCR) previously treated with an Oxaliplatin containing regimen.	IMP-239/2014	Concentrate for solution for infusionEach single vial contains 100 mg (100mg/5 mL) and 200 mg (200 mg/10 mL)...of Aflibercept.... 25mg/mL
125	Roche Products (India) Pvt.Ltd	Trastuzumab Emtansine	18-Dec-14	Is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer.	IMP-268/2014	powder for concentrate for solution for infusion.

126	Eli Lilly and Company Pvt. Ltd	Dulaglutide 1.5 mg single use pen & prefilled syringe	23-Dec-14	Indicated for type 2 Diabetes mellitus patients to improve glycaemic control as Monotherapy as well as Add-on Therapy.	IMP-267/2014	Concentrate solution for infusion in prefilled pen/syringe contains Delaglutide 0.75 mg / 1.5 mg in 0.5 mL
127	Roche Products (India) Pvt.Ltd	Pertuzumab	29-Dec-14	In combination with trastuzumab and docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer.	IMP-275/2014	Concentrate solution for infusion in vial or syringe contains Pertuzumab 420 mg
128	Roche Products (India) Pvt.Ltd	Obinutuzumab	2-Jan-15	In combination with Chlorambucil, is indicated for the treatment of patients with previously untreated Chronic Lymphocytic Leukemia (CLL).	IMP-280/2014	Concentrate for solution for infusion in vial contains Obinutuzumab 1000 mg in 40 mL vial
129	Eli Lilly and Company Pvt. Ltd	Zinc Insulin Crystals	03-Feb-15	---	Bulk-05/2015	
130	Lupin limited	Insulin Glargine Inj.	13-Feb-15	Insulin Glargine is indicated for once daily subcutaneous administration for treatment of adult patient with Type 1 Diabetes Mellitus or Type 2 Diabetes Mellitus who require basal (long acting) insulin for the control of hyperglycemia.	IMP-13/2015	SC injection.....Vial 10 mL and Cartridge 3 mL. Each vial/cartridge contains Insulin Glargine 100 IU/mL
131	Bayer Pharmaceuticals Pvt Ltd	Aflibercept	25-Feb-15	Indicated for the treatment of Neovascular (wet) age-related macular degeneration (wet AMD)	IMP-40/2015	Solution for intravitreal injection in PFS or vial.....Each single dose vial or PFS provide single dose of 50 µL containing 2 mg Aflibercept (40 mg/mL)
132	Roche Products (India) Pvt.Ltd	Interferon alfa- 2a (Roferon A)	13-Mar-15	Neoplasm, adjuvant to chemotherapy, solid Neoplasm, and for Viral disease.	IMP-058/2015	Solution for injection in Prefilled syringe contains Interferon alfa 2a 3 MIU/ 4.5 MIU in 0.5 mL
133	Novo Nordisk India Pvt Ltd	Insulin Crystals	17-03-2015	Bulk Drug	IMP-65/2015	Bulk Drug
134	Novo Nordisk India Pvt Ltd	Biphasic Insulin Aspart (Novomix)	13-Apr-15	treatment of type 1 and Type 2 diabetes mellitus patients	IMP-74/2015	Prefilled cartridge contains 300 Unit Insulin Aspart (100IU/mL)
135	Novo Nordisk India Pvt Ltd	Glucagon	13-Apr-15	Treatment of severe glycaemic reactions, which may occur in the management of insulin treated persons with diabetic mellitus.	IMP-73/2015	Lyophilized powder in vial co-packed with one syringe prefilled with sterilized WFI for reconstitution for injection. Each vial contains 1.0 mg Glucagon
136	Novartis India Pvt Ltd	Secukinumab	18-Jun-15	For the treatment of moderate to severe Plaque Psoriasis in adult Patients who are candidates for systemic Therapy, Psoriatic Arthritis and Ankylosing spondylitis	IMP-126/2015	1. Powder (Lyophilized) for solution for injection in vial 2. Solution for injection in pre-filled syringes/pre-filled pen., Each vial contains Secukinumab.....150 mg

137	Novo Nordisk India Pvt Ltd	Insulin degludec/ Liraglutide	10-Jul-15	For the treatment of adults with type 2 diabetes mellitus.	IMP-154/2015	Solution for SC injection in Cartridge (3 mL) assembeled in to Prefilled disposable pen injector contains 300IU Insulin degludec and 10.8 mg Liraglutide Strength: 300IU/mL Insulin degludec and 3.6 mg/mL Liraglutide
138	GlandPharma Ltd	Zinc Insulin Crystals	10-Aug-15		Bulk-177/2015	NA
139	Novo Nordisk India Pvt Ltd	Turoctocog alfa	19-Aug-15	Treatment and prophylaxis of bleeding in patients with Haemophilia A (Congenital factor)	IMP-182/2015	pwder (lyophilized) for solution for Injection for I.V. use., each vial contains 250IU, 500IU, 1000IU, 1500IU, 2000IU and 3000IU.
140	Sandoz Pvt. Ltd	Secukinumab	21-Aug-15	For the treatment of moderate to severe Plaque Psoriasis in adult Patients who are candidates for systemic Therapy, Psoriatic Arthritis and Ankylosing spondylitis	IMP-188/2015	Lyophilized powder for solution for injection in vial contains 150 mg/mL Secukinumab
141	Novo Nordisk India Pvt Ltd	Omalizumab	24-10-2015	Treatment of Persistant allergic asthma	Import-6200/05	75mg/150mg/vial
142	Glaxo Smith Kline pharmaceuticals ltd	Albiglutide powder	8-Dec-15	Albiglutide is indicated for the treatment of type 2 diabetes mellitus in adults to improve glycemic control as: Monotherapy: when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to contraindications or intolerance. Add-on combination therapy: In combination with other glucose- lowering medicinal products including basal insulin, when these, together with diet and exercise, do not provide adequate glycemic control.	IMP-234/2015	Power and solvent for solution for SC injection in pen delivers 30 mg/50 mg per 0.5 mL dose
143	Johnson and Johnson Pvt Ltd	Siltuximab	6-Jan-16	Siltuximab (SYLVANT®) is indicated for the treatment of patients with Multicentric Castleman's Disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.	IMP-257/2015	Powder for concentrate for solution for infusion in single use vial 100mg and 400mg

144	Baxalta Bioscience India Pvt Ltd	Coagulation factor IX (Rixubis)	21-Mar-16	Coagulation Factor IX (Recombinant) is an antihemophilic factor indicated for: Control and prevention of bleeding episodes in adults and children with hemophilia B Perioperative management in adults and children with hemophilia B Routine Prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia B	IMP-054/2016	Lyophilized powder for solution for IV use only.....Each Single vial contains 250IU, 500IU, 1000IU, 2000IU, 3000IU.....each vial to be reconstituted with 5 ml SWFI
145	Novartis Healthcare Pvt Ltd	Ofatumumab	12-Apr-16	Treatment of patients with progression of chronic lymphatic leukemia (CLL) after treatment with Fludarabine, Alemtuzumab and Rituximab, or patients for whom such combinations and other therapeutic alternative are ruled out. In combination with chlorambucil or bendamustine for treatment of patients with CLL who have not received prior therapy and who are not eligible for fludarabine based therapy.	IMP-059/2016	Concentrate for solution for infusion in Single use vial 100 mg/5 mL and 1000 mg/50 mL
146	Bristol Myers Squibb India Pvt. Ltd	Nivolumab concentrate for solution for infusion	9-Jun-16	Non-small cell lung cancer (NSCLC): Nivolumab as a single agent is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Renal cell carcinoma (RCC): Nivolumab as a single agent is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults.	IMP-88/2016	Concentrate for solution for infusion in Single use vial 40 mg/ 4 mL & 100 mg/10 mL

147	Eli Lilly and Company Pvt. Ltd	Ramucirumab	9-Jun-16	Ramucirumab in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Ramucirumab monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. Ramucirumab, in combination with Docetaxel, is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy.	IMP-89/2016	Concentrate for solution for infusion in Single use vial 100 mg/10 mL and 500mg/50 mL
148	MSD Pharmaceuticals Pvt. Ltd	Pembrolizumab	bookm	Is indicated for the treatment of patients with unresectable or metastatic melanoma	IMP-093/2016	Solution for IV infusion in single use vial 100 mg/4 mL

149	Sandoz Pvt. Ltd	Omalizumab	14-Jul-16	Allergic Asthma: A. Adult patients with moderate to severe persistent allergic asthma whose symptoms are inadequately controlled with inhaled corticosteroids. B. Children's (12 years of age and older)-omalizumab is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in in vitro reactivity to a perennial aeroallergen and who have reduced lung function (FEV₁<80%) as well as frequent day time symptoms or night-time awakening and who have had multiple documented severe asthma exacerbations despite daily high dose inhaled corticosteroids plus a long acting beta2-agonist. C. Children (6 to 12 years of age)-omalizumab is indicated as add-on therapy to improve asthma control in patients with severe persistent allergic asthma who have a positive skin test or in in vitro reactivity to a perennial aeroallergen and frequent day time symptoms or night-time awakening and who have had multiple documented severe asthma exacerbations despite daily high dose inhaled corticosteroids plus a long acting beta2-agonist. Chronic spontaneous urticarial (CSU)-Omalizumab is indicated for adults and adolescents (12 years of age and above) with chronic spontaneous urticarial refractory to standard of care.	IMP-101/2016	Dosage form: 1) Powder in Vial and solvent in ampoules for solution for injection 2) Solution for injection in prefilled syringe Strength: 75 mg and 150 mg
150	Sanofi-Synthelabo (India) Pvt. Ltd	Laronidase (Aldurazyme)	25-Jul-16	Aldurazyme is indicated for patients with Hurler and Hurler-Scheie forms of mucopolysaccharidosis I (MPS) and for patients with Scheie form who have moderate to severe symptoms.	IMP-124/2016	Solution for injection Each vial of 5 mL contains: Laronidase 2.9 mg
151	Sanofi-Synthelabo (India) Pvt. Ltd	Agalsidase Beta (Fabrazyme)	2-Aug-16	Agalsidase Beta is indicated for long term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry Disease (α-galactosidase A deficiency)	IMP-119/2016	Powder for concentrate for solution for infusion.....Each Single use vial contains: Agalsidase Beta 37 mg

152	Sanofi-Synthelabo (India) Pvt. Ltd	Thyrotropin alfa	2-Aug-16	Thyrotropin alfa is indicated for use as an adjunctive diagnostic tool for serum thyroglobulin testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer who have previously undergone thyroidectomy. Thyrotropin alfa is indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer	IMP-120/2016	Lyophilized Powder for solution for injection (For Intramuscular use only) in Single use vial Each single vial contains: Thyrotropin alfa 1.1 mg
153	Takeda Pharmaceuticals (India) Pvt. Ltd	Vedolizumab	5-Aug-16	Vedolizumab is indicated for the treatment of • Adult patients with moderately to severely active Ulcerative Colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or tumor necrosis factor-alpha (TNF- α) antagonist. • Treatment of adult patients with moderately or severely active Crohn's Disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or tumor necrosis factor-alpha (TNF- α) antagonist.	IMP-130/2016	Powder for concentrate for solution for infusion.....Each Single use vial contains: Vedolizumab 300 mg
154	Sanofi-Synthelabo (India) Pvt. Ltd	Imiglucerase (Cerezyme)	11-Aug-16	Cerezyme (Imiglucerase) is indicated for long term enzyme replacement therapy in patients with a confirmed diagnosis of non-neuropathic (Type 1) or chronic neuropathic (type 3) Gaucher disease and who exhibit clinically significant non-neurological manifestation of the disease.	IMP-135/2016	Powder for concentrate for solution for infusion in Single use vial Each single vial contains: Imiglucerase 200 units and 400 units
155	Sanofi-Synthelabo (India) Pvt. Ltd	Alglucosidase alfa (Myozyme)	29-Aug-16	Alglucosidase Alfa is indicated for long term enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of Pompe Disease (acid α -glucosidase deficiency)	IMP-143/2016	Lyophilized powder for concentrate for solution for IV Infusion in Single use vial Each single vial contains: Alglucosidase alfa 50mg
156	Biocon Limited	Insulin (Regular), soluble insulin, insulin IP	20.12.2016	Indicated for the treatment of diabetes mellitus	IMP-213/2016	Cartridge 3 mL (100 IU)
157	Johnson and Johnson Pvt Ltd	Daratumumab	2-Jan-17	Indicated for the treatment of patients with relapsed and refractory multiple myeloma, whose prior therapy included a protease inhibitor and an immunomodulatory agent.	IMP-223/2016	liquid concentrate for IV infusion after dilution in vial each mL contains 20 mg Daratumumab (5mL or 20 mL contain 100 mg or 400 mg)

158	Boehringer Ingelheim Pvt Ltd	Idarucizumab	5-Jan-17	Idarucizumab is a specific reversal agent for Dabigatran and is indicated in patients treated with Dabigatran Etexilate capsules when rapid reversal of the anticoagulant effects of Dabigatran is required: -For emergency surgery/urgent procedures. -In life threatening or uncontrolled bleeding.	IMP-224/2016	Solution for injection/infusion in vial each vial contains 2.5g/50mL (50mg/mL)
159	Amgen Technology Pvt. Ltd.	Evolocumab	15-Mar-17	Evolocumab injection 140 mg/mL is indicated in adults and adolescents aged 12 years and over with homozygous familial hypercholesterolaemia in combination with other lipid-lowering therapies	IMP-049/2017	Solution for injectionTwo presentations- (a) 1 Single use prefilled syringe with 27 gauge needle (b) 1 mL Single use prefilled SureClick Autoinjector with 27 gauge needle.....Each Prefilled Syringe or Autoinjector contains Evolocumab 140 mg/mL
160	Roche Products (India) Pvt.Ltd	Atezolizumab	31-Mar-17	Atezolizumab is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma after prior chemotherapy or who are considered cisplatin ineligible.	IMP-063/2017	Solution for infusion in vial 1200 mg
161	Biocad India Pvt Ltd	Rituximab	10-Jul-17	Rituximab is indicated for the treatment of Non-Hodgkin's Lymphoma, Rheumatoid Arthritis, Patients with relapsed or chemo-resistant Indolent B Cell Non-Hodgkin's Lymphoma, Previously untreated patients with chemotherapy, maintenance therapy for the treatment of Follicular Lymphoma patients responding to induction therapy, Patients with CD20 positive diffuse large B Cell Non-Hodgkin's Lymphoma in combination with CHOP chemotherapy, Chronic Lymphocytic Leukemia and Granulomatosis with Polyangitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangitis (MPA)	IMP-145/2017	Rituximab Concentrate for solution for infusion in vial100 mg/vial and 500 mg/vial
162	Sanofi-Synthelabo (India) Pvt. Ltd	Alemtuzumab	27-Jul-17	For treatment of patient with an aggressive form of relapsing remitting multiple sclerosis (RRMS) in whom there has been a failure of 1 first line disease modifying therapy.	IMP-146/2017	Concentrate for solution for infusion in vial (for IV use after dilution)..... Each vial contains Alemtuzumab 12 mg (Fill: 1.2 mL)
163	Eli Lilly and Company Pvt. Ltd	Insulin Glargine IP	21-Aug-17	For treatment of diabetes mellitus in adults adolescents and children aged 2 year and above	IMP-184/2017	Solution for injection for SC route Strength: 100 U/mL a) Cartridge (3mL) b) Prefilled Pen (3 mL)
164	Dr. Reddy's Laboratory	Denosumab	29-Aug-17	For prevention of skeletal related events in patients with advanced malignancies involving bone	IMP-185/2017	Solution for SC injection Each single use vial contains Denosumab 120mg (70 mg/mL)

165	Dr. Reddy's Laboratory	Ibritumomab	4-Sep-17	Relapsed or Refractory, Low-grade or Follicular NHL Previously untreated Follicular NHL	IMP-196/2017	IbritumomabTiuxetan injection for intravenous use 1.6 mg/ml (2 mL single use vial)
166	Dr. Reddy's Laboratory	Panitumumab (Vectibix)	14-Sep-2017	It is indicated as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) KRAS after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.	IMP-207/2017	Concentrate for solution for infusion 5 mL vial contains Panitumumab 100 mg (20 mg/mL)
167	Pfizer products India Pvt. Ltd	Moroctocog alfa	28-Sep-17	Moroctocogalfa, Antihemophilic Factor indicated for the control and prevention of hemorrhagic episodes and for routine and surgical prophylaxis in patients with hemophilia A	IMP-204/2017	Lyophilized powder for reconstitution (in a single use vial) 250IU or 500IU or 1000IU or 2000IU and one prefilled diluent syringe containing 4 mL 0.9% NaCl for reconstitution for IV injection
168	Dr. Reddy's Laboratory	Prolia (Denosumab)	8-Dec-17	Treatment of post-menopausal women with Osteoporosis at high risk for fracture. Treatment of increase bone mass in men with Osteoporosis.	IMP-226/2017	solution for subcutaneous injection in pre filled syringe contains 60 mg/ml
169	Shire Biotech India Pvt Ltd	Agalsidase alfa	18.01.2018	Indicated for long term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease (a-galactosidase A deficiency)	IMP-07/2018	Agalsidase alfa 1mg/ml concentrate for solution for injection
170	Shire Biotech India Pvt Ltd	Idursulfase	18.01.2018	Indicated for the treatment of the long term treatment of patients with Hunter Syndrome (Mucopolysaccharidosis MPS II)	IMP-06/2018	Idursulfase 2mg/ml concentrate for solution for intravenous infusion
171	Novo Nordisk India Pvt Ltd	Insulin aspart	18.01.2018	Treatment of diabetes mellitus	IMP-05/2018	Insulin aspart 3 ml prefilled pen (100IU/ml), 3ml cartridges (100U/ml) and 10ml vial (100U/ml)
172	Biocon Limited	Biphasic Isophane Insulin (30/70)	12.02.2018	Indicated for the treatment of diabetes mellitus	IMP-35/2018	Cartridge (3mL) (100IU/ml)
173	Biocon Limited	Insulin Injection (Neutral)	12.02.2018	Indicated for the treatment of diabetes mellitus	IMP-32/2018 Bulk-33/2018	Cartridge (3mL) (100IU/ml)
174	Biocon Limited	Isophane Insulin	12-Feb-18	Indicated for the treatment of diabetes mellitus	IMP-34/2018	Cartridge (3mL) (100IU/ml)

175	Vardhman Health Specialitis Pvt Ltd	Rituximab	20.02.2018	Indicated for the treatment of Non-Hodgkin's Lymphoma, rheumatoid arthritis, patients with relapsed or chemo-resistant indolent B cell Non-Hodgkin's Lymphoma, previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy, maintenance therapy for the treatment of follicular lymphoma patients responding to induction therapy, patients with CD20 positive diffuse large B cell Non-Hodgkin's Lymphoma in combination with CHOP chemotherapy, chronic lymphocytic leukaemia and granulomatosis with polyangitis (GPA) (Wegeners granulomatosis) and microscopic polyangitis (MPA).	IMP-43/2018	Rituximab concentrate for solution for infusion 10mg/ml
176	Pharose Remedies Ltd	Erythropoetin	01.03.2018	For treatment of anaemia due to chronic renal failure	IMP-51/2018	Injection in PFS or multi dose vials. 2000IU/3000IU/4000IU in PFS and 2000IU/3000IU/4000IU/6000IU/10000IU in multi dose vial
177	Eisai Pharmaceuticals India Pvt Ltd	Natalizumab	06.03.2018	Natalizumab is used for the treatment of: (a).. Relapsing form of Multiple Sclerosis (MS) Adult (b)...Patients aged 18 years and over with the high disease activity despite treatment with a beta interferon or Glatiramer acetate. These patients may be defined as those who have failed to respond to a full and adequate course (normally at least one year of treatment) or beta interferon or Glatiramer acetate.	IMP-026/2016	Natalizumab 300mg concentrate for solution for infusion
178	Eisai Pharmaceuticals India Pvt Ltd	Peg-Interferon Beta-1a	06.03.2018	Peg-interferon beta-1a injection (Plegridy) is indicated in adult patients for the treatment of relapsing remitting multiple sclerosis.	IMP-57/2016	Peg-Interferon Beta-1a injection 63mcg, 94 mcg, 125mcg/0.5ml PFS and prefilled pen

179	Eisai Pharmaceuticals India Pvt Ltd	Interferon Beta-1a	14.03.2018	Interferon beta-1a is indicated for the treatment of: (a). Ambulatory patients with relapsing multiple sclerosis characterized by at least 2 recurrent attacks of neurologic dysfunction (relapse) over the preceding 3 years period without evidence of continuous progression between relapse. Interferon beta-1a slows the progression of disability and decreases the frequency of relapses. (b). It is also indicated for the treatment of patients who have experienced a single demyelinating event with an active inflammatory process if it is severe enough to warrant treatment with intravenous corticosteroids, if alternative diagnosis have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.	IMP-027/2016	Interferon Beta-1a injection 30µgg/0.5ml PFS and prefilled pen
180	Roche Products (India) Pvt.Ltd	Emicizumab	19.03.2018	Indicated for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in patients with Hemophilia A (Congenital factor VIII deficiency) with factor VIII inhibitor	IMP-75/2018	Solution for injection, 30mg/vial, 60mg/vial, 105mg/vial, 150mg/vial
181	Eli Lilly and Company Pvt. Ltd	Olaratumab	02.04.2018	Indicated in combination with doxorubicin for the treatment of adult patients with advanced soft tissue sarcoma who are not amenable to curative treatment with surgery or radiotherapy and who have not been previously treated with doxorubicin.	IMP-108/2018	Olaratumab 190mg/19ml vial and 500mg/50ml vial
182	Biocad India Pvt Ltd	Trastuzumab	16-Apr-18	Trastuzumab is indicated for i. Treatment of neoadjuvant and adjuvant cancer with HER2 over expression. ii. Treatment of metastatic breast cancer with HER2 over expression. iii. Treatment of metastatic gastric cancer with HER2 over expression.	IMP-110/2018	Trastuzumab lyophilized powder for concentrate for solution for injection150mg (single use vial) and 440mg (multi use vial) trastuzumab
183	Shire Biotech India Pvt Ltd	Velaglucerase alfa	21.05.2018	Indicated for long-term enzyme replacement therapy in patients with type 1 Gaucher disease	IMP-109/2018	Velaglucerase alfa 400U/vial powder for solution for infusion

184	Astrazeneca Pharma India Ltd	Durvalumab	01.06.2018	1. Treatment of patients with locally advanced or metastatic urothelial carcinoma whose disease has progressed during or after platinum-based chemotherapy. 2. Treatment of patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) whose disease has not progress following platinum based chemotherapy	BIO/IMP/18/00001	Durvalumab 120 mg solution for infusion and 500mg solution for infusion
185	GSK Pharmaceuticals Ltd	Mepolizumab	12-Jun-18	Mepolizumab is indicated as add-on treatment for severe refractory eosinophilic asthma in adult patients	IMP-147/2018	Mepolizumab lyophilized powder for solution for injection in vial 100mg
186	Vardhman Health Specialitis Pvt Ltd	Trastuzumab 150mg and 440mg	25.06.2018	Trastuzumab is indicated for: i. Treatment of Neoadjuvant and adjuvant cancer with HER2 over expression. ii. Treatment of Metastatic breast cancer (MBC) with HER2 over expression. iii. Treatment of Metastatic Gastric cancer HER2 over expression	IMP/BIO/18/00005	Trastuzumab 150mg single use vial and Trastuzumab 440mg Multidose vial.
187	Biocon Limited	Insulin Glargine Injection (r-DNA) 100 IU/mL	28.08.2018	For the treatment of adults, adolescents and children of 2 years or above with Diabetes Mellitus, where treatment with insulin is required	IMP/BIO/18/000015	Cartridge of Insulin Glargine Injection (r-DNA) 100 IU/mL
188	Biocon Limited	Insulin Glargine (rDNA Origin) Bulk	05.09.2018	-----	IMP/BIO/18/000018	Insulin Glargine (r-DNA origin) Bulk (95% - 105 %)
189	Pfizer Products India Private Limited	Nonacog Alfa (recombinant coagulation factor IX)	05.09.2018	For the treatment of Prophylaxis of bleeding in patients with haemophilia B (Congenital factor IX deficiency)	IMP/BIO/18/000019	Dosage form: Powder and solvent for solution for injection Presentation: Vial (5 mL) Strength : 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU. Composition: Each mL Contains: 50 IU, 100 IU, 200 IU, 400 IU, 600 IU
190	Pfizer Products India Private Limited	Inotuzumab Ozagamicin (1mg) (0.25mg/1ml vial)	05.10.2018	Indicated as monotherapy for the treatment of adults with relapsed or refractory CD22-positive B cell precursor acute lymphoblastic leukaemia (ALL). Adult patients with Philadelphia chromosome positive (Ph+) relapsed or refractory B cell precursor ALL should have failed treatment with at least 1 tyrosine kinase inhibitor (TKI)	IMP/BIO/18/000023	Each vial contains 1 mg Inotuzumab Ozagamicin. After reconstitution, 1 mL of solution contains 0.25 mg Inotuzumab Ozagamicin.

[illegible]

[illegible]

