

Drugs Manufactured and marketed in India

S. No.	Name of the firm	Date of Permission	Permission No.	Name of the Drug	Indication	Dosage Form & Strength
1	Wockhardt Limited	22-Feb-07	MF-7206/07	Insulin Glargine 100 IU	For the treatment of type -I and Type -II diabetes mellitus patients who required basal (long acting) insulin for the control of hyperglycemia.	40 IU/ml (10 ml vial), 100 IU/ml (10 ml vial), 100 IU/ml (3 ml cartridge), 100 IU/ml (3 ml disposable pens) 15 ml vial also approved
2	Dr. Reddy's Laboratories Ltd.	23-Mar-10 20-Jul-10	MF-246/10 BULK-668/10	Darbepoetin alfa	Treatment of anaemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis and for the treatment of anaemia in patients with non-myeloid malignancies, where anaemia is due to the effect of concomitantly administered chemotherapy	Solution for injection in vial or prefilled syringe Strength: 1. Each 1 mL of single dose vial contains 25mcg, 40mcg, 60mcg, 100mcg, 200mcg, 300mcg and 500mcg 2. Each 0.75 mL of single dose vial contains 150mcg 3. Each 0.3 mL of single dose prefilled syringe contains 60mcg and 150mcg 4. Each 0.4 mL of single dose prefilled syringe contains 40mcg and 200mcg 5. Each 0.42 mL of single dose prefilled syringe contains 25mcg 6. Each 0.5 mL of single dose prefilled syringe contains 100mcg 7. Each 0.6 mL of single dose prefilled syringe contains 300mcg 8. Each 1 mL of single dose prefilled syringe contains 500mcg
3	Gennova Biopharmaceuticals Ltd.	29-Jan-10	MF-104/10	Pegfilgrastim (peg-r-hu-GCSF)	For prevention of neutropenia in the patient receiving cancer chemotherapy	Prefilled syringe for injection contains Pegfilgrastim 6 mg/0.6 mL
4	Gennova Biopharmaceuticals Ltd.	16-Mar-10	MF-229/10	Filgrastim (r-hu-GCSF)	cancer patients receiving myelosuppressive therapy	Solution for injection in prefilled Syringe and vial. Strength: 1. Each 1 mL of vial contains r-Hu-GCSF 300 mcg 2. Each 1.6 mL of vial contains r-Hu-GCSF 480 mcg 3. Each 1 mL of prefilled syringe contains r-Hu-GCSF 150 mcg 4. Each 0.5 mL of prefilled syringe contains r-Hu-GCSF 300 mcg 5. Each 0.8 mL of prefilled syringe contains r-Hu-GCSF 480 mcg
5	Virchow Biotech Pvt Ltd	28-Apr-10	MF-407/10	rh-PDGF-BB + β -TCP	For the treatment of preidontal defects (Intrabony Peridontal Defect, Peridontal Defect, Gingival Recession)	Mixture for Implantation in one pack contains following: one cup containing 0.5 cc of b-TCP particles (0.25 to 1.0 mm) and one syringe containing a solution of 0.5 mL of r-Hu-PGDF-BB (0.3 mg/mL)
6	Reliance Life Sciences Pvt Ltd	30-Apr-10	MF-436/10 MF-437/10	Recombinant Follicle stimulating hormone (r-Hu-FSH)	For the treatment of female infertility	Solution for injection in 2.7 mL multidose vial contains r-Hu-FSH 750IU/mL
7	Cadila Healthcare Ltd	28-Apr-10	MF-406/10	r-Hu-EPO Lyophilized injection	For maintaining hemoglobin level in chronic renal failure	Lyophilized powder for injection in vial contains r-Hu-EPO 1000IU/2000IU/4000IU/10000IU/40000IU

8	Intas Biopharmaceuticals Ltd	01-Nov-10	MF-893/10 BULK-892/10	Teriparatide [r-Hu-Parathyroid Hormone(1-34)].	Postmenopausal women with osteoporosis who are at high risk for fracture	Solution for injection in 3 ml pre filled cartridge contains Teriparatide 750 mcg
9	Dr. Reddy's Laboratories Ltd.	28-Jan-11	MF-05/2011	Pegfilgrastim	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes)	Solution for SC injection in 0.6 prefilled syringe contains Pegfilgrastim 6 mg
10	Reliance Life Sciences Pvt Ltd	04-May-11	MF-197/2011 BULK-198/2011	Recombinant Interferon Beta 1a	For the treatment of relapsing multiple sclerosis	Sub cutaneous injection in 0.5 mL prefilled syringe contains recombinant interferon Beta 1a 0.03 mg
11	Cadila Healthcare Ltd	21-Jun-11	MF-266/11	PegINF alfa 2b (lyophilized) (Subcutaneous)	In the treatment of Chronic Hepatitis B and C patients, in combination with ribavirin for the treatment of chronic hepatitis C in patient with compensated liver disease who have not been previously treated with interferon alfa 2b.	Lyophilized powder for SC injection in 0.5 mL vial contains 50mcg/80mcg/120mcg/150mcg Peg INF alfa 2b
12	Reliance Life Sciences Pvt Ltd	22-Jun-11	MF-262/11 BULK-261/11	r-Hu-Choriogonadotropin alfa	In treatment of women undergoing superovulation prior to assisted reproductive techniques such as IVF & anovulatory or oligo-ovulatory after stimulation of follicular growth	Solution for SC injection in prefilled Syringe Strength: 1. 0.2 mL of prefilled syringe contains 100mcg rhCG 2. 0.5 mL of prefilled syringe contains 250mcg rhCG

13	Gland Pharma Ltd	09-Aug-11	MF-334/2011	1. Biphasic Isophane Injection IP, 30% Soluble Insulin and 70% Isophane insulin 2. Biphasic Isophane Insulin Injection IP, 50% soluble Insulin and 50% Isophane insulin 3. Soluble Insulin injection IP 4. Isophane Insulin Injection IP	Treatment of Type-1 & Type-2 Diabetes	Sub cutaneous injection in vial Strength: 1. Biphasic Isophane Injection IP, 30% Soluble Insulin and 70% Isophane insulin 40IU/mL, 10 mL fill in 10 mL vial 2. Biphasic Isophane Insulin Injection IP, 50% soluble Insulin and 50% Isophane insulin 40IU/mL, 10 mL fill in 10 mL vial 3. Soluble Insulin injection IP 40IU/mL, 10 mL fill in 10 mL vial 4. Isophane Insulin Injection IP 40IU/mL, 10 mL fill in 10 mL vial
14	Bioviz Technologies pvt Ltd	09-Aug-11	MF-333/11	Erythropoetin (r-HU-EPO) injection	Anaemia resulted from renal function insufficiency, including hemodialysis and non-hemodialysis of chronic failure	Subcutaneous or IV injection in vial or Prefilled syringe. Strength: Each ml contains 2000IU or 4000IU of r-HU-EPO
15	USV Limited	13-Aug-12	MF-179/2012	Teriparatide	For the treatment of post -menopausal women with osteoporosis who are at a high risk of fracture . It increases bone mineral density (BMD) and reduces the risk of vertebral and non-vertebral fractures.	Solution for SC injection in 3 mL vial contains 750 mcg Teriparatide
16	Cadila Healthcare Ltd	21-Aug-12	MF-207/2012	Teriparatide	For the treatment of post -menopausal women with osteoporosis at a high risk of fracture	Solution for injection in vial or Cartridge. Strength: 1. Each 1.5 mL of vial contains Teriparatide 375 mcg and 2. Each 3 mL cartridge contains teriparatide 750 mcg
17	Virchow Biotech Pvt Ltd	28-Aug-12	MF-240/2012	Rasburicase injection	Prevention and treatment of malignancy associated hyperuricemia (in children and adults)	Lyophilized powder for solution for IV infusion in vial contains Rasburicase 1.5 mg or 7.5 mg per vial
18	USV Limited	06-Sep-12	Bulk-255/2012	Teriparatide	NA	NA

19	Biocon Limited	27-Dec-12	MF-376/2012, BULK- 377/2012	Itolizumab (T1hmAb) injection	For the treatment of patients with active to Moderate to severe chronic plaque psoriasis who are candidates for systemic therapy	Solution for IV injection in single use vial containing Itolozumab 25mg
20	Zenotech Laboratories	27-Feb-13	MF-36/2013	Rituximab	for the treatment of CD20 positive B-cell non-hodgkin's lymphoma	concentrate for solution for intravenous infusion in vial (10 mL or 50 mL) contains rituximab 100 mg or 500 mg
21	Intas Biopharmaceuticals	26-Feb-13	MF-05/2013	Rituximab	Rituximab is indicated for the treatment of • 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. • For patients with relapsed/refractory follicular lymphoma as maintenance therapy after responding to induction therapy with chemotherapy. • Patients with CD20 positive diffuse large B cell Non-Hodgkin's lymphoma in combination with CHOP (Cyclophosphamide, doxorubicin, vineristine, prednisolone) chemotherapy	concentrate for solution for intravenous infusion in vial (10 mL or 50 mL) contains rituximab 100 mg or 500 mg
22	Lupin limited	05-Mar-13	MF-22/2013	filgrastim	As an adjunct to Chemotherapy for prevention of Neutropenia in Patients with Non-Myeloid Malignancies	solution for injection in prefilled syringe and vial Strength: 300 mcg/0.5 mL PFS 60 MIU/mL 300 mcg/1 mL PFS/Vial 30 MIU/mL 480 mcg/0.8 mL PFS 60 MIU/mL 480 mcg/1.6 mL Vial 30 MIU/mL

23	Reliance Life Sciences Pvt Ltd	23-Apr-13	MF-87/2013	Abciximab	<p>Abciximab is indicated in the treatment of: As an adjunct to percutaneous coronary intervention for the prevention of cardiac ischemic complications • In patients undergoing percutaneous coronary intervention • In patients with unstable angina not responding to conventional medical therapy when percutaneous coronary intervention is planned within 24 hours.</p>	Solution for intravenous injection in vial contains 10 mg
24	Intas Biopharmaceuticals	25-Apr-13	MF-89/2013	Pegylated Recombinant Human Interferon alfa 2b	<p>Pegylated Recombinant Human Interferon alfa 2b injection is indicated for the treatment of Chronic hepatitis C and Chronic hepatitis B, in combination with ribavirin for the treatment of chronic Hepatitis C in patient with compensated liver disease who have not been previously treated with interferon alfa 2b.</p>	Lyophilized powder for solution for SC injections in vials and solvent for reconstitution in ampoule each vials contains 50 mcg/80mcg/ 150 mcg

25	Intas Biopharmaceuticals	14-May-13	MF-99/2013 BULK- 100/2013	Recombinant human Follicle stimulating hormone (Follitropin alfa)	1. Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to the treatment with Clomiphene citrate. 2. Controlled ovarian hyper stimulation to induce the development of multiple follicles in medically, assisted reproduction programmes (e.g. in vitro fertilization/embryo transfer (IVF/ET), gamete intra fallopian transfer (FIFT) and intra cytoplasmic sperm injection (ICSI)). 3. In association with Luteinizing Hormone (LH) preparation is recommended for the stimulation of Follicular development in women with severe LH & FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level <1.2 IU/l. 4. It is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human Chorionic Gonadotrophin (hCG) therapy.	solution for SC injection in prefilled syringe or cartridges or vial: strength: each multiple use prefilled cartridge contains 300 IU/0.48mL, 450 IU/0.72 mL, 600 IU/0.96 mL, 900 IU/1.4 mL each multiple use vial contains rhFSH 1200 IU/1.92 mL each single use prefilled syringe contain rhFSH 75 IU/0.12 mL and 150 IU/0.24 mL
26	Zenotech Laboratories	15-May-13	MF-6763/06	Recombinant human granulocyte macrophage colony stimulating factor (Molgramostim)	Recombinant Human Granulocyte Macrophage Colony Stimulating Factor (Molgramostim/r-hu-GM-CSF) is indication for the treatment of reduction of the severity of neutropenia in patients receiving myelosuppressive therapy (cancer chemotherapy)	lyophilized powder for solution for injection in single dose vial contains 400 mcg
27	USV Limited	03-Jun-13	MF-112/2013	Recombinant human growth hormone	Treatment of Pre-pubertal Children (4 to 12 years) with Growth Hormone Deficiency	lyophilized powder for solution for injection Each multiple use vial contains recombinant human growth hormone 5 mg

28	Lupin limited	03-Sep-13	MF-186/2013	Pegfilgrastim	For reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukemia and myelodysplastic syndromes)	solution for injection in prefilled syringe each prefilled syringe contains recombinant pegylated granulocyte colony stimulating factor (Pegfilgrastim) 6 mg/0.6 mL)
29	Cadila Pharmaceuticals	22-Oct-13	MF-135/2013	Filgrastim	for reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy for nonmyeloid malignancy	solution for subcutaneous injection in prefilled syringe contains filgrastim 300 mcg (1 mL)
30	Biocon limited	23-Oct-13	MF-241/2013 BULK-242/2013	Trastuzumab 150 mg/vial & 440 mg/vial	For the treatment of patients with Her2+ metastatic breast cancer	lyophilized powder for concentrate for solution for infusion in single and multiple use vials Strength: single use 150 mg trastuzumab multiple use vial 150 mg and 440 mg trastuzumab
31	Shantha Biotechnics Limited	14-Nov-13	MF-243/2013	Human insulin(Rapid)	Treatment of type-I or Type II diabetes mellitus	solution for injection in multidose (10 mL) vial contains human insulin 400 IU (40 IU/mL)
32	Biocon Limited	18-Nov-13	Bulk-256/2013	Nimotuzumab BULK	NA	protein concentration 4.8 to 5.2 mg/mL
33	Hetero Drugs Limited	06-Jan-14	MF-296/2013	Darbepoetin alfa	It is indicated for the treatment of Anemia with chronic renal failure including patients on dialysis and patients not on dialysis	Solution for injection in single dose prefilled syringe for subcutaneous injection Strength: 25 mcg/0.42 mL, 14 mcg/0.4 mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL/ 200 mcg/0.4 mL, 300 mcg/0.6mL and 500 mcg/1.0 mL
34	Hetero Drugs Limited	06-Jan-14	BULK-297/2013	Darbepoetin alfa Bulk	NA	1 mg/mL

35	Reliance Life Sciences Pvt Ltd	21-Mar-14	MF-61/2014	Infliximab	Rheumatoid Arthritis: · Reduction in signs & symptoms of rheumatoid arthritis in patients who have had an inadequate response to methotrexate · 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 · Use in early rheumatoid arthritis in patients with severe, active & progressive disease not previously treated with methotrexate or other DMARDs.	Lyophilized powder for intravenous infusion in vials contains 10 mg infliximab to be reconstituted with 10 mL WFI
36	Reliance Life Sciences Pvt Ltd	21-Mar-14	BULK-62/2014	Infliximab bulk	NA	25-35 mg/mL
37	Gennova Pharmaceuticals	29-Apr-14	BULK-87/2014	Tenecteplase Bulk	NA	not less than 5 mg

38	Intas Pharmaceuticals	30-Sep-14	MF-198/2014	Etanercept	<ul style="list-style-type: none"> · 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. 	Solution for injection in single use prefilled syringe contains Etanercept 25 mg/0.5 mL
39	Intas Pharmaceuticals	30-Sep-14	BULK-199/2014	Etanercept Bulk	NA	Strength: 55 mg/± 5 mg/ mL:
40	Cadila Healthcare Ltd.	25-Sep-14	MF-222/2014	Adalimumab	Treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.	Solution for SC injection in prefilled syringe contains Adalimumab 20mg and 40 mg
41	Cadila Healthcare Ltd	25-Sep-14	BULK-223/2014	Adalimumab	NA	NA
42	Cadila Healthcare Ltd	14-Oct-14	BULK-224/2014	r-Human Erythropoietin Conc. Solution	NA	NA
43	Shantha Biotechnics Limited	07-Nov-14	MF-236/2014	Insuman basal	Treatment of type-I or Type II diabetes mellitus	suspension for injection in vial contains 400 IU/10 mL
44	Shantha Biotechnics Limited	07-Nov-14	MF-237/2014	Insuman 25/75	Treatment of type-I or Type II diabetes mellitus	suspension for injection in vial contains 400 IU/10 mL
45	Scigen Biopharma Pvt ltd	03-Feb-15	BULK-12/2015	Recombinant Human Insulin	NA	NA

46	Eli Lilly and Company India Pvt. Ltd	03-Feb-15	Bulk-05/2015	Zinc Insulin Crystals Human, Proinsulin derived (r-DNA)	NA	NA
47	Reliance Life Sciences Pvt Ltd	12-Feb-15	BULK-16/2015	Rituximab (BULK)	NA	NA
48	Reliance Life Sciences Pvt Ltd	12-Feb-15	MF-17/2015	Rituximab	<p>1. Non-Hodgkin's Lymphoma (NHL) · Previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy. · Follicular lymphoma patients responding to induction therapy · Stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy. · Patients with CD20 positive diffuse large B cell Non- Hodgkin's lymphoma in combination with CHOP (Cyclophosphamide, doxorubicin, vincristine, and prednisolone) chemotherapy. 2. Rheumatoid Arthritis · For the treatment of adult patients with active rheumatoid arthritis who have an inadequate response or intolerance to one or more Tumor Necrosis Factor (TNF) inhibitor therapies and Pemphigus vulgaris (39 thSEC (Dermatology &Allergy) _14.03.2019)</p>	Concentrate for solution for IV infusion in vial of 10 mL and 50 mL containing Rituximab 100 mg or 500 mg (10 mg/mL)
49	Intas Pharmaceuticals Ltd	20-Feb-15	MF-35/2015 BULK-36/2015	Ranibizumab	<p>Ranibizumab is indicated for the treatment of the patients with: Neovascular age related macular degeneration (AMD) Diabetic Macular Oedema (DME) Macular Oedema following retinal vein occlusion (RVO) Vaisula imparment due to chroidal neovascularization (CNV) secondary to pathological myopia</p>	Solution for injection in single use vial of 0.23 mL contains 2.3 mg of Ranibizumab (10 mg/mL)

50	Wockhardt Limited	25-Feb-15	MF-41/2015	Pegfilgrastim (Peg-GCSF)	For prevention of Neutropenia in subjects receiving myelosuppressive chemotherapy in non-myeloid malignancies	Solution for SC injection in prefilled syringe or vial containing pegfilgrastim 6 mg/0.6 mL
51	Bharat Serum & vaccines Pvt Ltd	02-Mar-15	MF-59/2015	Human tetanus Immunoglobulin (HTIG) Injection	Tetanus Immunoglobulin (monoclonal) is to be prescribed for Adults only in the following indications: <ul style="list-style-type: none"> · Indicated for Prophylaxis against Tetanus following injury in patients whose immunization is incomplete or uncertain. It should be administered with appropriate wound management. · Also used therapeutically in the treatment of the tetanus, the recommended dose being 30 to 300 units/Kg body weight given intramuscularly into different sites. 	Solution for Intramuscular/intrathecal injection in single use vial contains 250 IU/500 IU/1000 IU in 1 mL
52	Hetero Drugs Limited	25-Mar-15 30-Mar-15	MF-76/2015 BULK-78/2015	Rituximab	For the treatment of the patients with <ul style="list-style-type: none"> · Non-Hodgkin's lymphoma (NHL) · Diagnosed Chronic Lymphocytic Leukemia (CLL) and also Pemphigus vulgaris (in Nov 2019) 	Concentrate for solution for IV infusion in Single use vial 100mg/10ml & 500 mg/50 ml
53	Intas Pharmaceuticals Ltd	13-Apr-15	MF-84/2015 BULK-83/2015	Peg-EPO	Peg-EPO is indicated for treatment of anaemia associated with chronic renal failure (CRF) in adults, including patients on dialysis and not on dialysis.	Solution for injection in prefilled Syringe or Vial Strength: 1.PFS: 30/50/75/100/120/150/200/250 mcg in 0.3 mL and 360/800mcg in 0.6 mL 2.Vial: 50/100/200/300/1000 mcg in 1 mL
54	Cadila Healthcare Ltd	12-May-15	BULK-111/2015	Peg-GCSF (Filgrastim)	NA	Strength: 12 (±1.2) mg/mL

55	Reliance Life Sciences Pvt Ltd	02-Jun-15	MF-120/2015 Bulk-119/2015	Trastuzumab	<p>1. Adjuvant Breast Cancer Trastuzumab is indicated for adjuvant treatment of HER2 over expressing node positive or node negative (ER/PR negative or with one high risk feature breast cancer • as part of a treatment regimen consisting of Doxorubicin, Cyclophosphamide, and either Paclitaxel or Docetaxel • with Docetaxel and Carboplatin • as a single agent following multi- modality anthracycline based therapy 2. Metastatic Breast Cancer Trastuzumab is indicated for • in combination with paclitaxel for first line treatment of HER2 over- expressing metastatic breast cancer • as a single agent of treatment of HER2 over expressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease 3. Metastatic Gastric Cancer Trastuzumab is indicated in combination with Cisplatin and Capecitabine or 5-fluorouracil for the treatment of patients with HER2 over expressing metastatic gastric or gastro esophageal junction adenocarcinoma who have not received prior treatment</p>	Lyophilized powder for concentrate for solution for IV infusion in vial contains 150 mg or 440 mg drug
56	Reliance Life Sciences Pvt Ltd	26-Jun-15	MF-150/2015 Bulk-149/2015	Adalimumab	<p>Rheumatoid Arthritis (RA) (in adults)(Moderate to severe, Active RA, Severe, active and progressive RA) Juveline Idiopathic Arthritis · Psoriatic Arthritis · Ankylosing Spondylitis and Axial Spondyloarthritis · Crohn's disease · Ulcerative colitis</p>	Solution for injection for SC injection in pre filled syringe contains 20 mg or 40 mg Adalimumab (50 mg/mL)
57	Cadila Healthcare Pvt. Ltd.	14-Jul-15	Bulk-80/2015	Filgrastim	NA	NA
58	Bharat Serum & vaccines Pvt Ltd	20-Jul-15	Bulk-67/2015	Human tetanus Immunoglobulin (HTIG) Injection	NA	NA
59	Cadila Healthcare Pvt. Ltd.	28-Oct-15	MF-209/2015 Bulk-210/2015	Trastuzumab	Treatment of patients with HER2 positive metastatic breast cancer.	Lyophilized powder for infusion in single and multiple use vial. Strength: 150 mg single use vial and 440 mg multiple use vial.
60	Reliance Life Sciences Pvt Ltd	05-Jan-16	MF-48/2016 BULK-49/2016	Bevacizumab	Indicated for the treatment of metastatic colorectal cancer (mCRC).	Concentrate for solution for IV infusion in Single use vial 100mg/4ml & 400 mg/16 ml

61	Reliance Life Sciences Pvt Ltd	13-May-16	MF-73/2016 BULK-74/2016	Pegfilgrastim (Peg-GCSF)	Chemotherapy induced neutropenia: Reduction of the risk of infectious complications (as manifested by febrile neutropenia) in patients with nonmyeloid malignancies receiving myelosuppressive antineoplastic therapy that is associated with a clinically important risk of severe neutropenia with fever.	Solution for injection for SC in Pre filled syringe 6mg/0.6 mL
62	Hetero Drugs Limited	13-May-16	MF-63/2016 BULK-62/2016	Bevacizumab	Bevacizumab in combination with XELOX and FOLFOX-4 is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC).	Concentrate for solution for IV infusion in Single use vial 100mg/4ml & 400 mg/16 ml
63	Reliance Life Sciences Pvt Ltd	14-Jun-16	MF-91/2016 BULK-92/2016	Darbepoetin alfa	1. Anaemia due to chronic kidney disease: Darbepoetin alfa is indicated for the treatment of anaemia due to chronic kidney disease, including patients on dialysis and patients not on dialysis. 2. Anaemia due to chemotherapy in patients with cancer: Darbepoetin alfa is indicated for the treatment of anaemia in patients with non-myeloid malignancies where anaemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation, there is a minimum of two additional months of planned chemotherapy.	Solution for injection in Prefilled syringe 25 µg, 40 µg, 60 µg, 100 µg, 150 µg, 200 µg, 300 µg, 500 µg

64	Intas Pharmaceuticals Ltd	23-Jun-16	MF-65/2016 BULK-64/2016	Bevacizumab	Bevacizumab, in addition to platinum based chemotherapy, is indicated for first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-small cell lung cancer other than predominantly squamous cell histology.	Concentrate for solution in Single use vial for IV infusion Strength: 100 mg/4 mL and 400 mg/16 mL
65	Cadila Pharmaceuticals limited	09-May-16	BULK-70/2016 dated 9 May 2016 (Form 46A)	Filgrastim Concentrate solution (BULK)	NA	Strength: not less than 0.9 mg/mL
66	Serum Institute of India	07-Jun-16	MF-79/2016 dated 7 June 2016 (Form 46)	Rabies Human Monoclonal antibody (Rabishield)	Rabies Human Monoclonal antibody is indicated as passive antibody component of post exposure prophylaxis of rabies infection, when given to individuals with suspected a rabies exposure. It must always be used along with a rabies vaccine as part of the post-exposure prophylaxis, as per recommendation of World Health Organization (WHO)	Solution for injection in Single use vial 100IU/2.5ml & 250IU/2.5 ml
67	Syngene International Limited	20-Dec-16	BULK-215/2016 dated 20 Dec 2016 Form 46A (for export purpose only)	Recombinant streptokinase (BULK)	NA	NA
68	Biocon Limited	01-May-17	MF-90/2017 BULK-91/2017	Bevacizumab	In treatment of patients with Metastatic colorectal Cancer, Non-Squamous Non-Small Cell Lung Cancer, Metastatic Breast cancer, Glioblastoma, Metastatic Renal cell carcinoma, Persistent, Recurrent, or Metastatic Carcinoma of the Cervix, Epithelial Ovarian and Fallopian tube or Primary Peritoneal Cancer	Concentrate for solution in single use vial for iv use (100mg/4ml and 400mg/16ml per vial)

69	Cadila Healthcare Ltd	12-May-17	MF-097/2017	Bevacizumab	For the treatment of patients with Metastatic Colorectal Cancer, Non-Squamous Non-Small Cell Lung Cancer, Metastatic Breast Cancer, Glioblastoma, Metastatic Renal Cell Carcinoma, Persistent, Recurrent or Metastatic Carcinoma of the Cervix, Epithelial Ovarian, Fallopian tube or Primary Peritoneal Cancer	Bevacizumab solution for intravenous infusion 100 mg/4 ml and 400 mg/16 ml
70	Serum Institute of India	15-May-17	BULK-81/2017	Rabies Human Monoclonal antibody (Rabishield)	NA	Each mL rabies human monoclonal antibody contains 100 IU
71	Bharat Serum & vaccines Pvt Ltd	23-May-17	MF-111/2017	Recombinant Human Chorionic Gonadotropin for injection (r-hCG)	r-hCG is indicated in the treatment of women undergoing superovulation prior to assisted reproductive technologies such as in vitro fertilization (IVF); R-hCG is administered to trigger final follicular maturation and luteinization after stimulation of follicular growth Anovulatory oligo ovulatory women: r-hCG is indicated in the treatment of anovulatory infertility where its administration is used would form part of recognized treatment regimen involving the prior stimulation of follicular maturation and endometrial proliferation	Injection for subcutaneous use in vial or prefilled syringe Strength: 6500 IU/vial or PFS

72	Hetero Drugs Limited	26-Jul-17	MF-124/2017 BULK-125/2017	Adalimumab	Adalimumab is indicated for the treatment of: Rheumatoid Arthritis (RA), Juvenile Idiopathic Arthritis, Axial Spondyloarthritis, Psoriatic Arthritis, Psoriasis, Paediatric Plaque Psoriasis,, Hidradenitis Suppurativa, Crohn's Disease, Paediatric Crohn's disease, Ulcerative colitis and Uveitis.	Adalimumab 50 mg/mL. 10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL in single use prefilled glass syringe and 40 mg/0.8 mL in single use glass vial. Injections for SC use.
73	Cadila Healthcare Ltd	10-Jan-18	MF-208/2017 Bulk-209/2017	Follitropin alfa	<p>a) In adult Women</p> <p>a. An ovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate.</p> <p>b. Stimulation of multi-follicular development in women undergoing super-ovulation for assisted reproductive technologies (ART) such as in vitro fertilization (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.</p> <p>c. FSH in association with a luteinizing hormone (LH) preparation is recommended for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.2 IU/L.</p> <p>b) In adult Men</p> <p>FSH is indicated for stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human Chorionic Gonadotropin (hCG) therapy.</p>	<p>Sterile solution for Multidose injection in prefilled glass cartridges: Follitropin alfa 300IU/0.48ml, 450IU/0.72ml and 900IU/1.44ml.</p> <p>Sterile lyophilized powder for solution for injection: 75IU (single use)</p>

74	Intas Pharmaceuticals Ltd	10-Jan-18	MF-284/2017 BULK- 286/2017	Denosumab 60mg/ml PFS	<p>Indicated for</p> <ul style="list-style-type: none"> i. treatment of postmenopausal women with osteoporosis at high risk for fracture. ii. Treatment to increase bone mass in men with osteoporosis at high risk of fracture. Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer - Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. 	Denosumab 60mg/ml in single use PFS and vial
75	Dr. Reddy's Laboratories Ltd.	06-Mar-18	MF-69/2018 BULK- 70/2018	Trastuzumab	<ul style="list-style-type: none"> 1. Trastuzumab is indicated for the treatment of adult patients with HER2 positive early breast cancer. 2. for the treatment of adult patients with HER2 positive metastatic breast cancer. 3. In combination with Capecitabine or 5-fluorouracil and cisplatin for the treatment of adult patients with HER2 positive metastatic adenocarcinoma of the stomach or gastroesophageal junction who have not received prior anticancer treatment for their metastatic disease who have not received prior treatment for metastatic disease. 	Trastuzumab 150mg and 440mg vials

76	Reliance Life Sciences Pvt Ltd	21-Mar-18	MF-89/2018 BULK-90/2018	Tenecteplase	Indicated in adults for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left bundle branch block within 6 h after the onset of acute myocardial infarction symptoms	Lyophilised powder and solvent for solution for injection 30mg/vial, 40/vial and 50mg/vial
77	Intas Pharmaceuticals Ltd	06-Apr-18	MF-119/2018 BULK-120/2018	Trastuzumab	<p>Trastuzumab is indicated for</p> <ol style="list-style-type: none"> i. The treatment of the patients with metastatic breast cancer who have tumors that over express HER2. ii. In combination with an aromatase inhibitor for the treatment of patients with HER2 positive and hormone receptor positive metastatic breast cancer. iii. Trastuzumab is indicated for the treatment of patients with HER2 positive early breast cancer following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable). iv. Trastuzumab is indicated for adjuvant treatment of HER2 over expressing node positive or node negative (ER/PR negative or with high risk feature) breast cancer. v. As part of a treatment regimen consisting of doxorubicin, cyclophosphamide and either paclitaxel or docetaxel vi. With docetaxel and carboplatin, trastuzumab is indicated for the treatment of patients with HER2 positive early breast cancer in combination with 	Trastuzumab lyophilized powder for concentrate for solution for injection. Each vials contains 150mg and 440mg trastuzumab

78	Reliance Life Sciences Pvt Ltd	07-May-18	MF-124/2018 BULK-125/2018	Etanercept	<p>Etanercept is indicated for reducing signs and symptoms -</p> <ul style="list-style-type: none"> · Including major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active Rheumatoid Arthritis (RA). Etanercept can be initiated in combination with methotrexate (MXT) or used alone. · of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients ages 2 years and older. · Inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). Etanercept can be used with or without Methotrexate. · In patients with active Ankylosing Spondylitis (AS) · Etanercept is indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. 	Etanercept injection lyophilized multi-use vial containing 25mg per vial.
79	Reliance Life Sciences Pvt Ltd	21-May-18	MF-145/2018 BULK-146/2018	Somatropin	Indicated for the treatment of paediatrics patients with growth failure due to inadequate secretion of endogenous growth hormone. For the treatment of paediatric patients with short stature associated with Noonan syndrome. For the treatment paediatrics patients with short stature born small for gestational age (SGA) with no catch-up growth by age 2-4 years.	Somatropin injection 3.33mg/ml vial

80	MJ Biopharma pvt ltd	14-Jun-18	MF/BIO/18/00001	Human Insulin, IP/Ph. Eur (As 30% Soluble Insulin Injection and 70% as Isophane Insulin Injection) 40 IU and 100 IU	Treatment of patients with diabetes mellitus, maintenance of normal glucose homeostasis in patients with diabetes	10 ml vial (40IU/ml), 10ml vial or 3ml cartridge (100IU/ml)
81	Dr. Reddy's Laboratories Ltd.	04-Sep-18	MF/BIO/18/00025	Bevacizumab	<ol style="list-style-type: none"> 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 	Bevacizumab Concentrate for Solution for Infusion Single use vial - 400 mg/ 16 mL, 100 mg/4 mL, (25 mg/mL)
82	Lupin Limited	05-Mar-19	MF/BIO/BD/19/000011	Etanercept drug substance	NA	Etanercept drug substance (r-DNA origin) 50 ± 5 mg/mL
83	Lupin Limited	05-Mar-19	MF/BIO/19/00011	Etanercept	For the treatment of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Nonradiographic Axial Spondyloarthritis (nrAxSpA), Plaque Psoriasis (PsO), Pediatric Plaque Psoriasis and Juvenile Idiopathic Arthritis (JIA).	Solution for subcutaneous Injection (single use) i. 50 mg/mL in Prefilled pen and Pre-filled Syringes ii. 25 mg /0.5 mL in Pre-filled Syringes

84	M/s. Intas Pharmaceuticals Ltd., 2 nd Floor, Chinubhai Centre Off. Nehru Bridge, Ashram Road Ahmedabad Gujarat (India) – 380009	01-Apr-19	Bulk-24/2019	Romiplostim drug substance	NA	Each mL contains 0.5 mg/mL ± 10% (0.45 mg/mL to 0.55 mg/mL) of Romiplostim
85	M/s. Intas Pharmaceuticals Ltd., 2 nd Floor, Chinubhai Centre Off. Nehru Bridge, Ashram Road Ahmedabad Gujarat (India) – 380009	01-Apr-19	MF-23/2019	Romiplostim	For chronic immune thrombocytopenic purpura (ITP) patients one year of age and older who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.	Romiplostim
86	M/s. Cadila Healthcare Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42, To 47 SarkhejBavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India)- 382213	16-Aug-19	MF/BIO/19/00041	Docaravimab and Miromavimab (r-DNA origin)	Docaravimab and Miromavimab is indicated for post exposure prophylaxis in individuals with suspected rabies exposure. Twinrab must always be used in combination Rabies vaccine as part of post exposure prophylaxis in line with the recommendation of World Health Organization (WHO)	Docaravimab and Miromavimab (r-DNA origin) Liquid solution for injection in Vial 3000.00 IU / 10 mL, 1500.00 IU / 2.5 mL, 3000.00 IU / 5 mL and 600.000 IU/ml
87	M/s USV Private Limited, C2 Community Centre Naraina Vihar, New Delhi-110028, India	12-Sep-19	MF/BIO/19/00044	Pegfilgrastim Injection	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy with malignancy (with the exception of Chronic Myeloid Leukaemia and Myelodysplastic syndromes).	Pegfilgrastim Injection (rDNA origin) Dosage form: Solution for Injection Composition: Each Prefilled Syringe contains: Pegfilgrastim.....6 mg/0.6 mL