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List of new drugs (r-DNA origin) approved for manufacture and marketing in India during Jan, 2020 – Dec, 2025						
S. No.	**Name of the firm**	**Date of Permission**	**Permission No. /CDSCO Reference No.**	**Name of the Drug**	**Indication**	**Dosage Form & Strength**
1	M/s Reliance Life Sciences Pvt. Ltd.	21-02-2020	MF/BIO/20/000009	Omalizumab powder for solution for Injection	**Asthma** Omalizumab is indicated for adult patients with moderate to severe persistent asthma who have a positive skin test or invitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Limitations of Use: • Omalizumab is not indicated for the relief of acute bronchospasm or status asthmaticus. • Omalizumab is not indicated for treatment of other allergic conditions. **Chronic Idiopathic Urticaria (CIU)** Omalizumab is indicated for the treatment of adult patients with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment. Limitation of Use: • Omalizumab is not indicated for treatment of other forms of urticaria.	Dosage Form: Lyophilized Powder for solution for Injection; Strength: 150 mg. Omalizumab powder for solution for Injection (subcutaneous route) 1. Single Use Vial (Single vial containing lyophilized product in the strength of 150 mg) 2. Combikit
2	M/s Reliance Life Sciences Pvt. Ltd.	26-02-2020	MF/BIO/20/000011	Omalizumab (new bulk drug substance) (90.00 mg/ml to 110.00 mg/ml)	Not applicable	Omalizumab (new bulk drug substance) (90.00 mg/ml to 110.00 mg/ml)
3	M/s Reliance Life Sciences Pvt. Ltd	30-03-2020	MF/BIO/20/000024	Ranibizumab Injection	Indicated for the Neovascular (Wet) Age-Related Macular Degeneration (AMD).	Dosage Form: Solution for Injection in vial. Strength: Ranibizumab 0.5 mg -10mg/ml (2.3 mg/0.23ml) - Ranibizumab 0.3 mg - 6mg/ml (1.38 mg /0.23

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						ml) 1. Single Use Vial (Single vial containing of 0.5 mg or o.3 mg Ranibizumab) 2. Combikit
4	M/s Reliance Life Sciences Pvt. Ltd	3-04-2020	MF/BIO/20/000026	Ranibizumab bulk drug substance	Not applicable	Ranibizumab bulk drug substance 12 mg/mL to 18 mg/mL
5	M/s USV Private Limited	13-04-2020	MF/BIO/20/000030	Pegfilgrastim bulk drug substance	Not applicable	Pegfilgrastim bulk drug substance
6	M/s Biocon Biologics India Limited	21-09-2020	MF 378/2012	Itolizumab Injection (r- DNA origin) 100 mg/vial lyophilized powder	• Treatment of patients with active moderate to severe chronic plaque psoriasis who are candidates for systemic therapy. • Restricted Emergency Use in the country for the treatment of Cytokine Release Syndrome (CRS) in moderate to severe Acute Respiratory Distress Syndrome (ARDS) patients due to COVID-19	Lyophilized powder for i.v injection. Each vial of Itolizumab Injection is reconstituted with approximately 1.1 mL of sterile water for injection. This results in a protein concentration of approximately 100 mg/mL Strength: 100mg/mL
7	M/s Biocon Biologics India Limited	22-09-2020	BULK - 377/2012	Itolizumab bulk drug substance (r-DNA origin)	Not applicable	Itolizumab bulk drug substance (r-DNA origin) 27±2 mg/mL, inhouse specification
8	M/s Mylan Pharmaceuticals Private Limited	07-01-2021	MF/BIO/21/000005	Etanercept	Rheumatoid Arthritis (RA)–□Etanercept in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate.□Etanercept can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate□Etanercept is also indicated in the treatment of severe, active and	Dosage Form: Solution for subcutaneous Injection (single use)

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					progressive rheumatoid arthritis in adults not previously treated with methotrexate. □Etanercept, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical functionJuvenile Idiopathic Arthritis (JIA) — □Treatment of polyarthritis (rheumatoid factor positive or negative)and extended oligoarthritis in children and adolescents from the age of 2 years who have had aninadequate response to, or who have proved intolerant of, methotrexate.□Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.□Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.□Etanercept has not been studied in children aged less than 2 years.Psoriatic Arthritis (PsA) –Treatment of active and progressive psoriatic arthritis in adults when the response to previous diseasemodifying antirheumatic drug therapy has been inadequate. Etanercept has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease.Axial spondyloarthritisAnkylosing Spondylitis (AS)– Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.Nonradiographic Axial Spondyloarthritis (nr-AxSpA)-Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal	Strength: Pre- filled syringe:(i)50 mg/mL in Prefilled Syringes (ii) 25 mg /0.5 mL in Pre-filled Syringes Pre-filled Pen: (i). 50 mg/mL Pre-filled pen

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					anti-inflammatory drugs (NSAIDs).Plaque Psoriasis (PsO) -Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy, including ciclosporin, methotrexate or psoralenand ultraviolet-A light (PUVA).Pediatric Plaque Psoriasis-Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	
9	M/s Mylan Pharmaceutical Private Limited	11-01-21	Bulk-BIO/03/2021	Etanercept drug substance (r- DNA origin)	NA	Protein Concentration 50 ± 5 mg/mL
10	M/s Cadila Healthcare Limited	12-01-2021	MF/BIO/21/000008	Trastuzumab emtansine, bulk	NA	Trastuzumab emtansine (r-DNA origin) Bulk drug substance; (Protein Concentration18.00 –22.00 mg/mL), in-house specification
11	M/s Enzene Biosciences Limited	28-01-2021	MF/BIO/21/000014	Teriparatide	Teriparatide is indicated in adults. Treatment of osteoporosis in postmenopausal women	i) Teriparatide Injection 600mcg/ 2.4 mL Pack style – 1 Disposable Pen of 600 mcg/2.4 mL (ii) Teriparatide Injection 750mcg/ 3 mLReusable pen with cartridge in blisters
12	M/s Cadila Healthcare Limited	23-04-21	MF-266/11, dated 21.06.2011	Pegylated Interferon alfa- 2b	**Additional indication** - Restricted Emergency Use in the country in emergency situation in the treatment of moderate COVID-19 infection in adults	Pegylated Interferon alfa-2b for Injection (r-DNA origin) 50 µg/0.5ml, 80 µg/0.5ml, 100 µg/0.5ml, 120 µg/0.5ml and 150 µg/0.5ml powder for concentrate for solution for infusion in single use vial (lyophilized vial for

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						subcutaneous)
13	M/s Epygen Biotech Private Limited	21-05-21	MF/BIO/21/000046	Biphasic Isophane Insulin Injection IP	Treatment of Diabetes mellitus	Dosage form: Suspension for Injection for subcutaneous administration Strength: 40 IU/ml, 10 mL vials
14	M/s Enzene Biosciences Ltd	01-07-21	MF/BIO/21/000056	Romiplostim injection	Romiplostim is indicated for the treatment of primary immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).	Dosage Form: Lyophilized powder for solution for injection in single use vial to be used as solution for Injection for subcutaneous use after reconstitution Strength: Romiplostim Injection (r-DNA Origin) 125 mcg/vial, 250 mcg/vial and 500 mcg/vial
15	M/s Enzene Biosciences Ltd	01-07-21	MF/BULK/BD/190/2021	Recombinant Romiplostim drug substance	NA	Recombinant Romiplostim drug substance 0.50 ± 10% mg/mL (0.45 to 0.55 mg/mL)
16	M/s Enzene Biosciences Ltd., Plot No. 165/1/26, Block 'T', Bhosari M.I.D.C Area, Bhosari, Pune – 411026, Maharashtra, India	20-07-2021	MF/BIO/21/000062	Denosumab 60mg/ml (r-DNA origin)	Denosumab is indicated for the treatment of osteoporosis in postmenopausal women.	solution for subcutaneous Injection in prefilled syringe Concentration: 60mg/ml
17	M/s Enzene Biosciences	20-07-2021	MF/BULK/BD/211/2021	Denosumab (r-DNA origin)	NA	Concentration: 90 ± 20 mg/mL (70 to

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	Ltd., Plot No. 165/1/26, Block 'T', Bhosari M.I.D.C Area, Bhosari, Pune – 411026, Maharashtra, India			drug substance		110 mg/mL)
18	M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, NarimanPoint, Mumbai (India) - 400021	16-08-2021	NOC for additional Strength & presentation-Pre Filled Syringe (PFS) vide F.No. BIO/MA/21/000052	Recombinant Human Follicle Stimulating Hormone I.P.	For the treatment of an ovulation in women, non-responsive toclomiphene citrate.	Dosage Form: Solution for Injection in Prefilled Pen for multidose usage Strength:450 IU/0.75ml
19	M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, NarimanPoint, Mumbai (India) - 400021	16-08-2021	NOC for additional Strength BIO/MA/21/00005	Recombinant Human Follicle Stimulating Hormone I.P.	For the treatment of an ovulation in women, non-responsive toclomiphene citrate.	Dosage Form: Solution for Injection in Prefilled Pen for multidose usage Strength: 900 IU/1.5mL
20	M/s. Intas Pharmaceuticals Ltd Corporate House, Near Sola Bridge S.G. Highway,	22-08-2021	MF/BIO/21/000083	Denosumab	• Prevention of skeletal related events in patients with advanced alignancies involving bone, • Prevention of skeletal related events in patientswith multiplemyeloma, • Treatment of adults and skeletally mature adolescents withgiant cell tumour of bone that is unresectable or where surgical	Dosage Form: Solution for injection in vial Strength: 70 mg/ml

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	Thaltej Ahmedabad Gujarat (India) – 380054				resection is likely to result in severe morbidity, • Treatment of hypercalcemia of alignancy refractory tobisphosphonate therapy	
21	M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, Nariman Point, Mumbai – 400 021, Maharashtra, India	24-08-2021	NOC for additional strength vide F. No. BIO/MA/21/000046	Recombinant Anti Rho-D Immunoglobulin	Indicated to prevent Rh Negative Women from forming antibodies to foetal rhesus positive red blood cells, that may pass in to the maternal blood during child birth, abortion or certain other sensitizing events	Dosage Form: Solution for injection for intramuscular administration only Strength: 150 mcg in 2 ml Vial
22	M/s Biopharma Limited, H.No. 8-3-166/1 & 2, 105 to 108, 1st Floor, G Block, East Wing, Challa Hyderabad - 500018, Telangana, India	03-09- 2021	MF/BULK/BD/259 /2021	Tocilizumab drug substance (r-DNA origin)	NA	Concentration: 20 mg/mL
23	M/s Biopharma 105 to 108, 1st Floor, G Block, East Wing, Challa	03-10-2021	MF/BIO/21/000104	Tocilizumab	Indicated for Restricted use of the drug under emergency situation in the country to treat COVID-19 hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)	Dosage Form: Concentrate for solution for infusion in single use vial Strengths - (i) 80 mg/4 mL (ii) 200 mg/10mL (iii) 400 mg/20mL

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24	M/s Lupin Limited, Kalpataru Inspire, 3rd Maharashtra, India	29-10-2021	MF/BULK/BD/314/2021	Ranibizumab drug substance (r-DNA origin)	NA	Concentration: 9.5 –11 mg/mL
25	M/s Lupin Limited, Kalpataru Inspire, 3rd Maharashtra, India	29-10-2021	MF/BIO/21/000119	Ranibizumab	Indicated for the treatment of neovascular (wet) age – related macular degeneration (AMD)	Dosage Form: Solution for intravitreal injection in vial Strength – 10 mg/mL
26	M/s Biogenomics Limited, First Floor, Kothari Compound, Opposite Tiku-ji-ni-wadi, Maharashtra, India	29-10- 2021	MF/BULK/BD/312/2021	Recombinant Insulin Aspart I.P. (r-DNA origin) drug substance	NA	lyophilized powder
27	M/s Biogenomics Limited, First Floor, Kothari Compound, Opposite Tiku-ji-ni-wadi Mandapa, Thane West - 400610, Maharashtra, India	29-10-2021	MF/BIO/21/000120	Recombinant Insulin Aspart I.P.	Indicated for treatment of diabetes mellitus (DM) in adults	Dosage Form: Solution for injection Strength - 100 U/mL or 3.5 mg/mL of Insulin aspart in 3 mL cartridge and 10 mL vial
28	M/s Cadila Healthcare Limited	30.12.2020	MF/BIO/20/000102	Trastuzumab Emtansine	1) **Metastatic Breast Cancer (MBC)** for the treatment of HER2-positive, unresectable locally advanced or metastatic breast cancer, in patients who had previously received trastuzumab and a	Dosage Form: Lyophilized Powder for concentrate for solution for Intravenous infusion in

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					taxane, separately or in combination. Such patients should have either i) received prior therapy for locally advanced or metastatic disease, or ii) developed a disease recurrence during or within six months of completing adjuvant therapy. 2) **Early Breast Cancer (EBC)** for the adjuvant treatment of patients with HER2-positive early breast cancer with residual invasive disease in the breast and/or lymph nodes after receiving neo-adjuvant taxanebased and HER2-targeted therapy	Vial Strength: 100 mg and 160 mg
29	M/s Virchow Biotech Pvt Ltd., Plot No: 4, SV Cooperative, Industrial Estate, Jeedimetla Medchal – Malkajgiri (D), Telangana - 500055, India	29-12-2021	MF/BIO/21/000140	Pegylated Recombinant Human Granulocyte Colony Stimulating factor injection	Reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the expectation of chronic myeloid leukemia and myelodysplastic syndromes).	Dosage Form: Solution for injection in pre- filled syringe Strength - 6mg/0.6ml.
30	M/s Dr Reddys Laboratories Limited, Survey No. 47, Bachupally Village, Bachupally Mandal, Hyderabad (India) – 500090	29-12-2021	MF/BIO/21/000141	Rituximab (r-DNA origin) Bulk FDS	NA	Frozen or liquid condition
31	M/s Bharat Serums and Vaccines Limited, 17th	19-01-2022	NOC vide F. No. BIO/MA/21/000054	Recombinant Human Follicle Stimulating Hormone	For the treatment of an ovulation in women, non-responsive toclomiphene citrate.	Dosage Form: Solution for injection in prefilled pen(Multidose)

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	Floor, Hoechst House, NarimanPoint, Mumbai (India) - 400021					Strength - 1200 I.U. / 2.0 mL
32	M/s Dr Reddys Laboratories Limited, Survey No. 47, Bachupally Village, Bachupally Mandal, Hyderabad (India) – 500090	20-04-2022	MF/BIO/22/000030	Bevacizumab Formulated Drug Substance in Liquid and Frozen form (r-DNA origin)	NA	Concentration: 25 mg/mL
33	M/s Anamay Biotech Private Limited, 2, Padmja	23-05-2022	MF/BIO/22/000045	Recombinant Human Epidermal Growth Factor Aqueous Bulk	NA	Concentration: NLT 500 µg in 1mL
34	M/s Anamay Biotech Private Limited, 2, Padmja	23-05-2022	MF/BIO/22/000046	Recombinant Human Epidermal Growth Factor, Silver Sulfadiazine and Chlorohexidine Gluconate Cream	For the Treatment of burns	Dosage Form: Topical Cream Strength: Quantity per gram: • Recombinant Human Epidermal Growth Factor - 10mcg, • Silver Sulfadiazine- 1% • Chlorohexidi ne Gluconate- 0.2%
35	M/s Anamay Biotech Private Limited, 2,	24-05-2022	MF/BIO/22/000048	Recombinant Human Epidermal Growth Factor	indicated for the topical healing of diabetic foot ulcers, donor site skin grafts and burn wounds	Dosage Form: Topical gel Strength: 10 µg,

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	Padmja					60 µg and 150 µg Topical gel
36	M/s Lupin Limited, Kalpataru Inspire, 3rd Floor, Off Western Express Highway, Santacruz (East), Mumbai – 400055, Maharashtra, India	17-06-2022	NOC for additional indications vide F. No. BIO/MA/22/000031	Ranibizumab	1. The treatment of visual impairment due to diabetic macular oedema (DME), 2. The treatment of macular edema following retinal vein occlusion (RVO), 3. The treatment of visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM)	Dosage Form: Solution for injection in Vial Strength: 10 mg/ml
37	M/s Intas Pharmaceuticals Limited	06-07-2022	PAC for additional indication vide F.No. 4-93/Intas/PAC-R-Ranibizumab/2021-BD	Ranibizumab	Ranibizumab is indicated in preterm infants for the treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), Zone II (Satge 3+) or AP-ROP (aggressive posterior ROP) disease".	Dosage Form: Solution for injection in vial Strength: 10 mg/mL
38	M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, India	22-08-2022	NOC for new strength vide F. No. BIO/MA/22/000060	Recombinant Human Follicle Stimulating Hormone	For the treatment of an ovulation in women, non-responsive to clomiphene citrate.	Dosage Form: Solution for Injection in Prefilled Pen for multidose usage Strength: 300 IU/0.5ml
39	M/s Bharat Serums and Vaccines Limited, 17th	29-09-2022	NOC for additional presentation-Pre Filled Syringe (PFS) vide F. No. BIO/MA/21/000115	Recombinant Anti Rho-D Immunoglobulin	r-anti-D is indicated to prevent Rh Negative Women from forming antibodies to foetal rhesus positive red blood cells, that may pass in to the maternal blood during child birth, abortion or certain other sensitizing events.	Dosage Form: Solution for injection in Pre-filled syringe for intramuscular administration only Strength: 150 mcg / 1mL
40	M/s Enzene Biosciences Ltd.	28-10-2022	MF/BIO/22/000100	Adalimumab (r-DNA Origin)	Adalimumab is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.	Dosage Form: Solution for injection in PFS. Strength: 100 mg/mL

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41	M/s Enzene Biosciences Ltd.	08-12-2022	MF/BIO/21/000014	Teriparatide	1) Treatment of postmenopausal women with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. 2) Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy. 3) Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.	Dosage Form: Solution for subcutaneous Injection Strength: 600 mcg/2.4ml and 750 mcg/3ml
42	M/s Reliance Life Sciences Private Limited	19-12-2022	MF/BIO/22/000133	Denosumab (r-DNA Origin)	Denosumab is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture.	Dosage Form: Solution for subcutaneous injection in PFS & vial. Strength: 60 mg/ml
43	M/s Enzene Biosciences Ltd.	16-01-2023	MF/BIO/23/000001	Cetuximab	Squamous cell cancer of the head and neck.	Dosage Form: Solution for Intravenous Infusion in vial Strength: 100 mg/20 ml
44	M/s. Hetero Biopharma Limited	31-01-2023	MF/BIO/23/000004	Tenecteplase	Tenecteplase is indicated in adults for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left Bundle Branch Block within 6 hours after the onset of acute myocardial infarction (AMI) symptoms	Dosage Form: Lyophilized powder for injection in vial Strength: 30 mg/6 ml, 40 mg/8 ml, 50 mg/10 ml
45	M/s Wockhardt Limited	14-02-2023	MF/BIO/23/000006	Erythropoietin	Anaemia associated with chronic renal failure in haemodialysis in adults or peritoneal dialysis and non-dialysed adults	Dosage Form: Solution for injection in PFS. Strength: 4000IU, 5000IU, 10000IU
46	M/s Enzene Biosciences Ltd.	21-02-2023	MF/BIO/23/000011	Bevacizumab	Bevacizumab in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum	Dosage Form: Concentrate for solution for infusion in Vial Strength: 25 mg/ml
47	M/s Sun Pharmaceutical Industries Limited	24-03-2023	MF/BIO/23/000020	Ranibizumab	Indicated for the treatment of neovascular age-related macular degeneration (AMD)	Dosage Form: Single-use glass vial for intravitreal injections Strength: 10 mg/mL

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48	M/s Enzene Biosciences Ltd.	10-04-2023	MF/BIO/23/000031	Denosumab injection	• Treatment to increase bone mass in men with osteoporosis at high risk of fracture. • Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture. • Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer. • Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer	Dosage Form: Pre-filled syringe Strength: 60 mg/ml
49	M/s Reliance Life Sciences Pvt. Ltd.	26-04-2023	MF/BIO/23/000038	Golimumab Injection	Golimumab in combination with methotrexate (MTX), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis	Dosage Form: Solution for injection in Single use prefilled syringe for subcutaneous injection. Strength: 50 mg/0.5 mL and 100 mg/mL
50	M/s Reliance Life Sciences Pvt. Ltd.	26-04-2023	MF/BIO/23/000037	Ustekinumab	Ustekinumab is indicated for the treatment of adult patients with moderate to severe plaque psoriasis.	Dosage Form: Solution for injection in Single use prefilled syringe for subcutaneous injection. Strength: 45 mg/0.5 mL and 90 mg/mL
51	M/s Reliance Life Sciences Pvt. Ltd.	16-05-2023	MF/BIO/23/000046	Ustekinumab Drug Substance (Bulk)	NA	Concentration: 95.00 to 125.00 mg/mL
52	M/s Reliance Life Sciences Pvt. Ltd.	16-05-2023	MF/BIO/23/000047	Golimumab Drug Substance (Bulk)	NA	Concentration: NLT 110 mg/mL
53	M/s Shilpa Biologicals Private Limited	22-06-2023	MF/BIO/23/000057	Adalimumab	Adalimumab is indicated for Rheumatoid Arthritis (RA) (in adults) • Moderate to severe, active RA • Severe, active and progressive RA	Dosage Form: Solution for Injection (Single use prefilled syringe for subcutaneous injection) Strength: 40 mg/0.4 mL
54	M/s Shilpa Biologicals Private Limited	24-08-2023	MF/BIO/23/000078	Adalimumab Drug Substance (Bulk)	NA	Concentration: 100 mg/ml
55	M/s Enzene Biosciences	29-08-2023	MF/BIO/23/000080	Ranibizumab Injection	Neovascular Age related Macular Degeneration	Dosage Form: Solution for injection in

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	Ltd.					vial Strength: 10 mg/ml
56	M/s Levim Biotech LLP	24-08-2023	MF/BIO/23/000076	Liraglutide	For the treatment of Type II Diabetes Mellitus.	Dosage Form: Solution for Injection in 3 ml cartridge (18mg/3mL) Strength: 10 mg/mL
57	M/s Zenotech Laboratories Limited	05-10-2023	MF/BIO/23/000089	Ranibizumab	Indicated for the treatment of neovascular age-related macular degeneration (AMD)"	Dosage Form: Single-use glass vial for intravitreal injections Strength: 10 mg/ml
58	M/s Gennova Biopharmaceuticals Limited	27-10-2023	MF/BIO/23/000093	Tenecteplase	**Revision of Approved Indication:** Tenecteplase (TNK-t-PA) is indicated in thrombolytic treatment of the Acute Ischemic Stroke within 4.5 hrs of the stroke initiation	Dosage Form: powder for injection. Strength: 20 mg/10mL Vial
59	M/s Reliance Life Sciences Pvt. Ltd.	29-11-2023	MF/BIO/23/000098 **Note:** Approval of Additional Indication.	Bevacizumab	**Additional Indication:** Hepatocellular Carcinoma (HCC) -Bevacizumab in combination with Atezolizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.	Dosage Form: Solution for infusion. Strength: 100 mg/4mL & 400mg/16mL
60	M/s Enzene Biosciences Ltd.	08-01-2024	MF/BIO/24/000002	Ranibizumab Drug Substance	NA	Concentration: 13 mg/mL ±10%
61	M/s Sun Pharmaceuticals Industries Limited	18-01-2024	MF/BIO/24/000006 **Note:** Approval of Additional Indication.	Ranibizumab	**Additional Indication:** 1. Diabetic Macular Oedema (DME). 2. Macular Oedema following Retinal Vein Occlusion (RVO). 3. Visual impairment due to Choroidal Neovascularization (CNV) secondary to Pathogenic Myopia (PM).	Dosage Form: Single-use glass vial for intravitreal injections Strength: 10 mg/mL
62	M/s M.J. Biopharm Pvt. Ltd	19-01-2024	MF/BIO/24/000011	Liraglutide	For the treatment of Type II Diabetes Mellitus.	Dosage Form: Single-use glass vial for intravitreal injection Solution for Injection in 3 ml cartridge Strength: 18 mg/3mL

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63	M/s Enzene Biosciences Ltd.	30-01-2024	MF/BIO/24/000014 **Note:** Approval of Additional Indication.	Bevacizumab	**Additional Indication:** 1. Metastatic colorectal cancer, in combination with fluoropyrimidine irinotecan or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line Bevacizumab-containing regimen. 2. Bevacizumab in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer. 3. Bevacizumab in combination with capecitabine is indicated for first-line treatment of adult patients with metastatic breast cancer in whom treatment with other chemotherapy options including taxanes or anthracyclines is not considered appropriate.Patients who have received taxane and anthracycline containing regimens in the adjuvant setting within the last 12 months should be excluded from treatment with bevacizumab in combination with capecitabine 4. 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. 5. Bevacizumab in combination with interferon alfa-2a is indicated for first line treatment of adult patients with advanced and/or metastatic renal cell cancer. 6. Bevacizumab in combination with carboplatin and paclitaxel is indicated for the front-line treatment of adult patients with advanced (International Federation of Gynecology and Obstetrics (FIGO) stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. 7. Bevacizumab in combination with carboplatin and gemcitabine or in combination with carboplatin and paclitaxel, is indicated for treatment of adult patients with first recurrence of platinum-sensitive epithelial ovarian, fallopian tube or primary peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor targeted agents. 8. Bevacizumab in combination with paclitaxel,	Dosage Form: Concentrate for solution for infusion in Vial. Strength: 100mg/4mL & 400 mg/16mL

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					topotecan, or pegylated liposomal doxorubicin is indicated for the treatment of adult patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than two prior chemotherapy regimens and who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor targeted agents. 9. Bevacizumab in combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, is indicated for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix. 10. Recurrent glioblastoma in adults. 11. Hepatocellular Carcinoma (HCC) in combination with atezolizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.	
64	M/s M.J. Biopharm Pvt. Ltd	27-03-2024	MF/BIO/24/000039	Recombinant Insulin Glargine, Drug Substance IP/USP/Ph. Eur	NA	NA
65	M/s M.J. Biopharm Pvt. Ltd	27-03-2024	MF/BIO/24/000037	Insulin Glargine Injection	For the treatment of patients diagnosed with Type 2 Diabetes Mellitus	Dosage Form: Solution for Injection in 10 ml vial and 3 ml cartridge Strength: 100 IU/mL
66	M/s Curateq Biologics Private Limited	27-03-2024	MF/BIO/24/000036	Trastuzumab(r-DNA origin) drug substance	NA	Concentration: 22mg/ml±1mg/ml (Frozen liquid) and 25mg/ml ±2mg/ml (Frozen liquid)
67	M/s Curateq Biologics Private Limited	27-03-2024	MF/BIO/24/000036	Trastuzumab	For the treatment of HER2-positive metastatic breast cancer	Dosage Form: Powder for concentrate for Solution for Infusion. Strength: 150mg/vial & 420mg/vial
68	M/s Zydus Lifesciences Limited	04-04-2024	MF/BIO/24/000041	Pertuzumab	For the treatment of metastatic breast cancer	Dosage Form: Single dose vial of concentrate solution for intravenous infusion

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						Strength: 420mg/14mL (30mg/mL)
69	M/s Enzene Biosciences Ltd.	29-04-2024	MF/BIO/24/000046 **Note:** Approval of Additional Indication	Adalimumab Injection	1.Rheumatoid arthritis 2.Psoriatic arthritis 3.Hidradenitis suppurativa (HS) 4.Crohn's disease 5.Ulcerative colitis 6.Psoriasis 7. Juvenile idiopathic arthritis	Dosage Form: Strength: 20 mg/ 0.2 mL PFS, 40 mg/ 0.4 mL PFS, 80 mg/ 0.8 mL PFS (100mg/mL)
70	M/s Biocon Biologics Limited	30-04-2024	MF/BIO/24/000047 **Note:** Due to change of MA holder	Etanercept Injection	Rheumatoid Arthritis (RA) – • Etanercept in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate. • Etanercept can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate • Etanercept is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. • Etanercept, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function **Juvenile Idiopathic Arthritis (JIA) –** • Treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. • Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. • Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy. • Etanercept has not been studied in children aged	Dosage Form: Solution for subcutaneous Injection (single use) Strength: 50mg/mL & 25mg/0.5mL in PFS and 50mg/mL in PFP

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					less than 2 years. **Psoriatic Arthritis (PsA) –** Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease modifying antirheumatic drug therapy has been inadequate. Etanercept has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease. **Axial spondyloarthritis** **Ankylosing Spondylitis (AS)** –Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. **Nonradiographic Axial Spondyloarthritis (nr-AxSpA)** -Treatment of adults with severe non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to nonsteroidal anti-inflammatory drugs (NSAIDs). **Plaque Psoriasis (PsO)** -Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy, including ciclosporin, methotrexate or psoralen and ultraviolet-A light (PUVA). **Pediatric Plaque Psoriasis** -Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.	
71	M/s Biocon Biologics Limited	30-04-2024	MF/BIO/24/000047 **Note:** Due to change of MA holder	Etanercept (r-DNA origin) drug substance (bulk);	Not Applicable	Composition: 45.00 mg/mL to 55.00 mg/mL, in-house specification
72	M/s Reliance Life Sciences Pvt Ltd	09.07.2024	MF/BIO/24/000077 **Note:** Approval of Additional Indication	Ranibizumab	1) Macular Edema Following Retinal Vein Occlusion (RVO) 2) Diabetic Macular Edema (DME) 3) Diabetic Retinopathy (DR) 4) Myopic Choroidal Neovascularization (mCNV)	Dosage Form: solution for injection in vial Strength: 2.3mg/0.23mL (0.5mg dose) and 1.38mg/0.23mL (0.3mg

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						dose)
73	M/s Zydus Lifesciences Limited	27.08.2024	MF/BIO/24/000091 **Note:** Approval of Additional Indication	Pertuzumab	Early Breast Cancer	Dosage Form: Concentrate solution for intravenous infusion in vial Strength: 420 mg/14 mL (30mg/mL)
74	M/s Bharat Serums And Vaccines Limited	15.10.2024	MF/BIO/24/000107 **Note:** Revised Indication	Trinbelimab	Trinbelimab Injection (r-anti-D) is indicated to prevent Rh negative women from forming antibodies to foetal Rh positive red blood cells, that may pass into the maternal blood during pregnancy, childbirth, abortion or certain other sensitizing events	Dosage Form: Solution for Injection in Vial and PFS Strength: 300 mcg & 150 mcg
75	M/s Reliance Life Sciences Pvt Ltd	25.10.2024	MF/BIO/24/000111 **Note:** Approval of Additional Indication	Golimumab	a) Golimumab alone or in combination with methotrexate,is indicated for the treatment of adult patients with active psoriatic arthritis. b) Golimumab is indicated for the treatment of adult patients with active ankylosing spondylitis. c) Golimumab is indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral amino salicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for: • inducing and maintaining clinical response • improving endoscopic appearance of the mucosa during induction • inducing clinical remission • achieving and sustaining clinical remission in induction responders	Dosage Form: Solution for injection in PFS. Strength: 50mg/0.5ml and 100mg/ml
76	M/s Cadila Pharmaceuticals Limited	27.11.2024	MF/BIO/24/000126	Biphasic Isophane Insulin Injection (30/70) IP	For the treatment of Diabetes Mellitus in patients who requires injectable insulin.	Dosage Form: Solution for injection in Vial. Strength: 40IU/mL
77	M/s. Hetero Biopharma Limited	20.12.2024	MF/BIO/24/000132	Denosumab	Denosumab 120 mg/ 1.7 ml (70 mg/mL) (r-DNA origin) is indicated for- 1. Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with advanced malignancies involving bone.	Dosage Form: Subcutaneous (SC) Injection in Vial. Strength: 70mg/mL

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					2. Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity	
78	M/s Reliance Life Sciences Pvt. Ltd.	23.12.2024	MF/BIO/24/000133 **Note:** Approval of Additional Indication	Ustekinumab	1. Psoriatic Arthritis (PsA) UstekiRel® is indicated for the treatment of adult patients with active psoriatic arthritis. UstekiRel® can be used alone or in combination with methotrexate (MTX). 2. Crohn's Disease (CD) UstekiRel® is indicated for the maintenance treatment of adult patients with moderately to severely active Crohn's disease. 3. Ulcerative Colitis (UC) UstekiRel® is indicated for the maintenance treatment of adult patients with moderately to severely active ulcerative colitis	Dosage Form: Solution for injection in PFS. Strength: 45 mg/0.5ml & 90 mg/ml
79	M/s Zydus Lifesciences Limited	27.12.2024	MF/BIO/24/000136	Nivolumab	**1. Metastatic Non-Small Cell Lung Cancer** Nivolumab as a single agent is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. Nivolumab, in combination with ipilimumab, is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 (≥1%) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations. Nivolumab, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations. Nivolumab, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lungcancer (NSCLC). **2.Renal Cell Carcinoma** Nivolumab as a single agent is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) after prior therapy in adults. Nivolumab is indicated for the treatment of patients	Dosage Form: concentrate for solution for infusion. Strength: 40 mg/4 mL and 100mg/10mL (10mg/mL)

					with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with ipilimumab. Nivolumab, in combination with cabozantinib, is indicated for the first-line treatment of patients with advanced Renal cell carcinoma (RCC). **3.Squamous Cell Carcinoma of the Head and Neck (SCCHN)** Nivolumab as monotherapy is indicated for the treatment of recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based therapy. **4. Melanoma** Nivolumab as a single agent is indicated for the treatment of patients with BRAF V600 wildtype unresectable or metastatic melanoma Nivolumab as a single agent is indicated for the treatment of patients with BRAF V600 mutation positive unresectable or metastatic melanoma. Nivolumab is indicated for the treatment of patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant settings. **5.Classical Hodgkin Lymphoma** Nivolumab is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after: -autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or -3 or more lines of systemic therapy that includes autologous HSCT. **6. Urothelial Carcinoma** Nivolumab is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC. Nivolumab is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who: -have disease progression during or following platinum-containing chemotherapy. -have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy. **7. Colorectal Cancer (CRC)**	

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					Nivolumab as monotherapy is indicated for the treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. **8. Esophageal squamous cell carcinoma (ESCC)** Nivolumab is indicated for the treatment of unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine-and platinum-based chemotherapy. Nivolumab, in combination with fluoropyrimidine-and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC). **9. Gastric Cancer, Gastroesophageal Junction Cancer and Esophageal Adenocarcinoma** Nivolumab, in combination with fluoropyrimidine-and platinum-containing chemotherapy, is indicated for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma. **10. Adjuvant treatment of Resected Esophageal or Gastroesophageal Junction Cancer (EC or GEJC)** Nivolumab is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy (CRT).	
80	M/s Intas Pharmaceuticals Ltd.	17.01.2025	MF/BIO/25/000006	Pertuzumab, drug substance and drug product	For the treatment of HER2-positive Metastatic Breast Cancer -Pertuzumab is indicated in combination with trastuzumab and docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not yet received any chemotherapy for their metastatic disease	Dosage Form: Concentrate for Solution for Infusion in vial. Strength: 420 mg/14 mL (30 mg/mL)
81	M/s Shilpa Biologicals Private Limited	17.01.2025	MF/BIO/25/000005 **Note:**	Adalimumab	**1. Psoriasis:** Moderate to severe chronic plaque psoriasis in adult patients. **2. Hidradenitis Suppurativa (HS):** Active moderate to	Dosage Form: Solution for Injection (Single use prefilled syringe for

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			Approval for Additional Indication		severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **3. Crohn's disease (CD):** Adult patients with moderate to severe active CD who have had inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies. **4. Ulcerative Colitis (UC):** Adult patients with moderate to severe active UC who have had an inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies.	subcutaneous injection) Strength: 40 mg/0.4 mL
82	M/s Levim Lifetech Private Limited	28.02.2025	MF/BIO/25/000028 **Note:** Due to name change MA is re-issued.	Liraglutide Drug Substance (r-DNA origin), Liraglutide 6.0 mg/ml solution for injection	For the treatment of Type II Diabetes Mellitus	Dosage Form: Solution for Injection in 3 ml cartridge (18mg/3mL) Strength: 6.0 mg/mL
83	M/s Levim Lifetech Private Limited	01.04.2025	MF/BIO/25/000031 **Note:** Due to name change MA is re-issued.	Streptokinase Bulk Solution (r-DNA) origin (Ready-to-fill), Recombinant Streptokinase for Injection, I.P. 15,00,000 IU	Acute Myocardial Infraction	Dosage Form: Lyophilized powder for solution for Injection Strength: 15,00,000 IU/vial
84	M/s Reliance Life Sciences Pvt Ltd	28.04.2025	MF/BIO/25/000062 **Note:** Approval for Additional Indication	Denosumab	For the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity	Dosage Form: Solution for Subcutaneous injection in a single use vial Strength: 120mg /1.7 ml
85	M/s Enzene Biosciences Ltd.	13.06.2025	MF/BIO/25/000085	Pertuzumab injection (rDNA origin) 420 mg/14mL (Single dose vial with a concentration of 30mg/mL	HER2-positive Metastatic Breast Cancer	Dosage Form: Solution for infusion (Intravenous) Strength: 30mg/mL
86	M/s. Zydus Lifesciences Limited,	19.06.2025	MF/BIO/25/000092	Aflibercept 40 mg/mL (2mg/0.05mL) (r-DNA origin)	1. Neovascular (wet) age-related macular degeneration (AMD) 2. Macular oedema secondary to RVO (branch RVO or central RVO) 3. Visual impairment due to Diabetic Macular Oedema (DME) 4. Visual impairment due to Diabetic Retinopathy (DR)	Dosage Form: Sterile solution for intravitreal injection. Strength: 40 mg/mL

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					5. Visual impairment due to Myopic Choroidal Neovascularization (myopic CNV)	
87	M/s Regenix Biosciences Limited	23.06.2025	MF/BIO/25/000096	Insulin Glargine Injection IP 100IU/mL (r-DNA Origin)	For the treatment of patients diagnosed with Type 2 Diabetes Mellitus	Dosage Form: Solution for Injection in 10 ml vial, 3 ml cartridge and 3 ml cartridge in disposable pen. Strength: 100IU/mL
88	M/s. Zydus Lifesciences Limited	23.06.2025	MF/BIO/25/000093	Rituximab 100 mg/10 mL and 500mg/50mL (10mg/mL) (r-DNA origin)	**1. Rheumatoid arthritis** Zydus Rituximab in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies. Zydus Rituximab has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate. **2. Non-Hodgkin's lymphoma (NHL)** - Zydus Rituximab is indicated for the treatment of previously untreated adult patients with stage III-IV follicular lymphoma in combination with chemotherapy. - Zydus Rituximab maintenance therapy is indicated for the treatment of adult follicular lymphoma patients responding to induction therapy. - Zydus Rituximab monotherapy is indicated for treatment of adult patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy. - Zydus Rituximab is indicated for the treatment of adult patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy. - Zydus Rituximab in combination with chemotherapy is indicated for the treatment of paediatric patients (aged 6 months to less than Page 3 of 6 18 years old) with previously untreated advanced stage CD20 positive diffuse large B-cell lymphoma (DLBCL),	Dosage Form: Single dose vial, Concentrate for solution for intravenous infusion. Strength: 10mg/mL

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					Burkitt lymphoma (BL)/Burkitt leukaemia (mature B-cell acute leukaemia) (BAL) or Burkitt-like lymphoma (BLL)	
89	M/s. Hetero Biopharma Limited	03.07.2025	MF/BIO/25/000099	Denosumab Formulated Drug Substance (r-DNA origin) 70mg/mL	NA	Strength: 70mg/mL
90	M/s Virchow Biotech Private Limited	04-08-2025	MF/BIO/25/000114	Rituximab Injection 500mg/50mL and 100 mg/10mL (r-DNA origin)	i. Rheumatoid Arthritis ii. Non–Hodgkin's Lymphoma (NHL) iii. Chronic Lymphocytic Leukemia (CLL) iv. Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) v. Pemphigus Vulgaris (PV)	Dosage Form: Solution for infusion (Intravenous) in 10mL and 50mL vial. Strength: 500mg/50mL and 100 mg/10mL
91	M/s Biogenomics Limited	29.08.2025	MF/BIO/25/000127	Biphasic Insulin Aspart Injection I.P. (r-DNA origin), 100 IU/ml in 3ml Cartridge and VD Pen 60 (Mixture of insulin aspart and protamine crystallised insulin aspart)(30:70)	Treatment of Diabetes Mellitus in Adults 30 years and above.	Dosage form: Suspension for injection for s. c. use. Strength: 100 IU/ml in 3ml Cartridge and VD Pen 60
92	M/s Biocon Biologics Limited	14.11.2025	MF/BIO/25/000156	1. Trastuzumab Lyophilized powder for injection 150 (mg) (r-DNA origin) multiple use vial (Combipack) supplied along with Bacteriostatic Water for injection containing 1.1% Benzyl alcohol. (10 mL Bacteriostatic Water for Injection will be supplied along with the product). 2. Trastuzumab Lyophilized powder	1.Adjuvant Breast Cancer • Trastuzumab is indicated in adults for adjuvant treatment of HER2overexpressing node positive or node negative (ER/PR negative or with one high risk feature in breast cancer. • As part of a treatment regimen consisting of doxorubicin, cyclophosphamide and either paclitaxel or docetaxel. • As part of a treatment regimen with docetaxel and carboplatin • As a single agent following multi-modality anthracycline based therapy. 2. Metastatic Breast Cancer Trastuzumab is indicated in adults • In combination with paclitaxel for first-line treatment of HER2 – overexpressing metastatic breast cancer.	Dosage form: Lyophilized powder for solution for injection. Strength: 150 mg / 440 mg

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				for injection 440 mg (r-DNA origin) multiple use vial (combipack) supplied along with Bacteriostatic Water for injection containing 1.1% Benzyl alcohol. (2 x 10 mL Bacteriostatic Water for Injection will be supplied along with the product).	• As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. **3. Metastatic Gastric Cancer** Trastuzumab indicated in adults, in combination with cisplatin and capecitabine or 5-fluorouracil for the treatment of patients with HER2- overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease.	
93	M/s Zydus Lifesciences Limited	28.11.2025	MF/BIO/25/000160 **Note:** Approval for additional Strength	Bevacizumab	-	-
94	M/s Eris Lifesciences Limited	16.12.2025	MF/BIO/25/000164	Isophane Insulin Injection	For the treatment of diabetes mellitus in patients who requires injectable insulin.	Dosage form: Lyophilized powder for solution for injection. Strength: 150 mg / 440 mg
95	M/s Eris Lifesciences Limited	16.12.2025	MF/BIO/25/000165	Insulin Injection IP Soluble Insulin, Neutral (Regular)	For the treatment of diabetes mellitus in patients who requires injectable insulin.	Dosage form: Solution for injection Strength: 100 IU/mL, 3 ml Cartridge
96	M/s Eris Lifesciences Limited	16.12.2025	MF/BIO/25/000174	Biphasic Isophane Insulin Injection	For the treatment of diabetes mellitus in patients who requires injectable insulin	Dosage form: Solution for injection Strength: 100 IU/mL, 3 ml Cartridge
97	M/s Eris Lifesciences Limited	16.12.2025	MF/BIO/25/000179	Insulin Injection IP Soluble Insulin, Neutral (Regular)	For the treatment of Diabetes Mellitus	Dosage form: Solution for injection Strength: 100 IU/mL 10 mL Vial
98	M/s Eris Lifesciences Limited	16.12.2025	MF/BIO/25/000177	Insulin Glargine Injection IP	For the treatment of adults, adolescents and children of 6 years or above with diabetes mellitus, where treatment with insulin is required	Dosage form: Solution for injection Strength: 100 IU/mL (3 ml cartridge, 3 ml vial and 5 ml vial)
99	M/s Eris Lifesciences	16.12.2025	MF/BIO/25/000175	1. Biphasic Isophane Insulin Injection	Treatment of diabetes mellitus	Dosage form: Suspension for Injection

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	Limited			2. Biphasic Isophane Insulin Injection		Strength: (30/70) 40 IU/mL, 10 mL vial / (50/50) 40 IU/mL, 10 mL vial
100	M/s Eris Lifesciences Limited	16.12.2025	MF/BIO/25/000176	1. Biphasic Isophane Insulin Injection 2. Biphasic Isophane Insulin Injection	Treatment of diabetes mellitus	Dosage form: Suspension for Injection Strength: (30/70) 100 IU/mL, 10 mL Vial / 50/50) 100 IU/mL, 10 mL Vial
101	M/s Eris Lifesciences Limited	17.12.2025	MF/BIO/25/000168	1. Insulin Glargine IP (rDNA Origin) and 2. Insulin Glargine IP (rDNA Origin)	For the treatment of adults, adolescents and children of 6 years or above with Diabetes mellitus, where treatment with insulin is required.	Dosage form: Suspension for Injection Strength: 100 IU/mL, 10 mL Vial / 100 IU/mL, prefilled pen with 3 mL cartridge
102	M/s Eris Lifesciences Limited	17.12.2025	MF/BIO/25/000167	Insulin Injection IP Soluble Insulin (Neutral)	For the treatment of diabetes mellitus in patients who requires injectable insulin.	Dosage form: Solution for injection Strength: 40 IU/mL, 10 mL Vials
103	M/s Eris Lifesciences Limited	17.12.2025	MF/BIO/25/000178	Nimotuzumab Injection (Humanized Anti-EGFR monoclonal antibody)	For the treatment of head and neck cancer	Dosage form: Solution for injection Strength: 50 mg
104	M/s Enzene Biosciences Ltd.	19.12.2025	MF/BIO/23/000001 **Note:** Approval for Additional Indication	Cetuximab	1.Head and Neck Cancer: Treatment of patients with squamous cell cancer of the head and neck in combination with radiation therapy for locally advanced disease. 2. Colorectal Cancer: Treatment of patients with epidermal growth factor receptor (EGFR)- expressing, RAS wild-type metastatic colorectal cancer □ in combination with Irinotecan based chemotherapy □ in first-line in combination with FOLFOX □ as a single agent in patients who have failed oxaliplatin and irinotecan-based therapy and who are intolerant to irinotecan.	Dosage Form: Solution for Intravenous Infusion in vial Strength: 100 mg/20 ml
105	M/s Eris Lifesciences Limited	19.12.2025	MF/BIO/25/000182	Isophane Insulin Injection	For the treatment of diabetes mellitus in patients who requires injectable insulin.	Dosage form: Suspension for injection Strength: 40 IU/mL (10 m Vial)
106	M/s Genesys	29.12.2025	MF/BIO/25/000186	Insulin Glargine	For the Treatment of Type II Diabetes Mellitus in	Dosage form: Solution for

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	Biologics Pvt. Ltd.			Injection	Adults only	Injection in 3 ml cartridge Strength: 100 IU/mL
107	M/s Genesys Biologics Pvt. Ltd.	29.12.2025	MF/BIO/25/000187	Insulin Glargine I.P (r-DNA Origin) Drug Substance	-	-