

**Annexure 'B'**

List of new drugs (r-DNA origin) approved for manufacture and marketing in India during Jan, 2020 – Jun, 2024						
S. No.	Name of the firm	Date of Permission	Permission 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	<p><b>Asthma</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>• Omalizumab is not indicated for the relief of acute bronchospasm or status asthmaticus.</li> <li>• Omalizumab is not indicated for treatment of other allergic conditions.</li> </ul> <p><b>Chronic Idiopathic Urticaria (CIU)</b></p> <p>Omalizumab is indicated for the treatment of adult patients with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.</p> <p>Limitation of Use:</p> <ul style="list-style-type: none"> <li>• Omalizumab is not indicated for treatment of other forms of urticaria.</li> </ul>	<p>Dosage Form: Lyophilized Powder for solution for Injection;</p> <p>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</p>
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).	<p>Dosage Form: Solution for Injection in vial.</p> <p>Strength: Ranibizumab 0.5 mg -10mg/ml (2.3 mg/0.23ml) - Ranibizumab 0.3 mg - 6mg/ml (1.38 mg /0.23</p>

**Annexure 'B'**

						ml) 1. Single Use Vial (Single vial containing of 0.5 mg or 0.3 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	<ul style="list-style-type: none"> <li>• Treatment of patients with active moderate to severe chronic plaque psoriasis who are candidates for systemic therapy.</li> <li>• 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</li> </ul>	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)

**Annexure 'B'**

				<p>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</p> <p>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 less than 2 years.</p> <p>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.</p> <p>Axial spondyloarthritis Ankylosing Spondylitis (AS)– Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.</p> <p>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</p>	<p>Strength: Pre-filled syringe:(i)50 mg/mL in Prefilled Syringes (ii) 25 mg /0.5 mL in Pre-filled Syringes</p> <p>Pre-filled Pen: (i). 50 mg/mL Pre-filled pen</p>
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**Annexure 'B'**

					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 Pharmaceuticals 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	<b>Additional indication</b> - 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

**Annexure 'B'**

						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/21/2021	Denosumab (r-DNA origin)	NA	Concentration: 90 ± 20 mg/mL (70 to

**Annexure 'B'**

	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, Nariman Point, Mumbai (India) - 400021	16-08-2021	NOC for additional strength & presentation-Pre Filled Syringe (PFS) vide F.No. BIO/MA/21/00005 2	Recombinant Human Follicle Stimulating Hormone I.P.	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: 450 IU/0.75ml
19	M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, Nariman Point, 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 to clomiphene 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/21/00008 3	Denosumab	<ul style="list-style-type: none"> <li>• Prevention of skeletal related events in patients with advanced malignancies involving bone,</li> <li>• Prevention of skeletal related events in patients with multiple myeloma,</li> <li>• Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical</li> </ul>	Dosage Form: Solution for injection in vial  Strength: 70 mg/ml

**Annexure 'B'**

	Thaltej Ahmedabad Gujarat (India) – 380054				resection is likely to result in severe morbidity, <ul style="list-style-type: none"> <li>• Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy</li> </ul>	
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

**Annexure 'B'**

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 Sanofi Healthcare India Private	29-11-2021	MF/BIO/21/000126	Insulin Glargine (r-DNA origin) injection	Indicated for treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.	Dosage Form: Solution for injection in 3 mL cartridge

**Annexure 'B'**

	Limited, Sanofi House, CTS- 117B, L&T Business Park, Saki Vihar Road, Powai, Mumbai, - 400072, Maharashtra, India					Strength - 100 IU (Units)
29	M/s Virchow Biotech Pvt Ltd., Plot No: 4, SV Cooperativ e, Industrial Estate, Jeedimetla Medchal - Malkajgiri (D), Telangana - 500055, India	29-12-2021	MF/BIO/21/00014 0	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 myelodysplasticsyndromes).	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/21/00014 1	Rituximab (r- DNA origin) Bulk FDS	NA	Frozen or liquid condition

**Annexure 'B'**

31	M/s Bharat Serums and Vaccines Limited, 17th Floor, Hoechst House, Nariman Point, Mumbai (India) - 400021	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 to clomiphene citrate.	Dosage Form: Solution for injection in prefilled pen (Multidose)  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: <ul style="list-style-type: none"> <li>• Recombinant Human Epidermal Growth Factor - 10mcg,</li> <li>• Silver Sulfadiazine- 1%</li> <li>• Chlorohexidine Gluconate- 0.2%</li> </ul>

**Annexure 'B'**

35	M/s Anamay Biotech Private Limited, 2, Padmja	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, 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 (Stage 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

**Annexure 'B'**

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
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

**Annexure 'B'**

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
48	M/s Enzene Biosciences Ltd.	10-04-2023	MF/BIO/23/000031	Denosumab injection	<ul style="list-style-type: none"> <li>• Treatment to increase bone mass in men with osteoporosis at high risk of fracture.</li> <li>• Treatment of bone loss associated with long-term systemic glucocorticoid therapy in adult patients at increased risk of fracture.</li> <li>• Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer.</li> <li>• Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer</li> </ul>	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) <ul style="list-style-type: none"> <li>• Moderate to severe, active RA</li> <li>• Severe, active and progressive RA</li> </ul>	Dosage Form: Solution for Injection (Single use prefilled syringe for subcutaneous injection) Strength: 40 mg/0.4 mL
54	M/s Shilpa	24-08-2023	MF/BIO/23/000078	Adalimumab Drug	NA	Concentration: 100

**Annexure 'B'**

	Biologicals Private Limited			Substance (Bulk)		mg/ml
55	M/s Enzene Biosciences Ltd.	29-08-2023	MF/BIO/23/000080	Ranibizumab Injection	Neovascular Age related Macular Degeneration	Dosage Form: Solution for injection in 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 Genova Biopharmaceuticals Limited	27-10-2023	MF/BIO/23/000093	Tenecteplase	<b>Revision of Approved Indication:</b> 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	Bevacizumab	<b>Additional Indication:</b> 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	Ranibizumab	<b>Additional Indication:</b> 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

**Annexure 'B'**

						Solution for Injection in 3 ml cartridge
						Strength: 18 mg/3mL
63	M/s Enzene Biosciences Ltd.	30-01-2024	MF/BIO/24/000014  <b>Note:</b> Approval of Additional Indication.	Bevacizumab	<b>Additional Indication:</b> <ol style="list-style-type: none"> <li>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.</li> <li>2. Bevacizumab in combination with paclitaxel is indicated for first-line treatment of adult patients with metastatic breast cancer.</li> <li>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</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>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</li> </ol>	Dosage Form: Concentrate for solution for infusion in Vial.  Strength: 100mg/4mL & 400 mg/16mL

**Annexure 'B'**

					<p>peritoneal cancer who have not received prior therapy with bevacizumab or other VEGF inhibitors or VEGF receptor targeted agents.</p> <p>8. Bevacizumab in combination with paclitaxel, 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.</p> <p>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.</p> <p>10. Recurrent glioblastoma in adults.</p> <p>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.</p>	
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	<p>Dosage Form: Solution for Injection in 10 ml vial and 3 ml cartridge</p> <p>Strength: 100 IU/mL</p>
66	M/s Curateq Biologics Private Limited	27-03-2024	MF/BIO/24/000036	Trastuzumab(r-DNA origin) drug substance	NA	<p>Concentration: 22mg/ml±1mg/ml (Frozen liquid) and 25mg/ml ±2mg/ml (Frozen liquid)</p>
67	M/s Curateq Biologics Private Limited	27-03-2024	MF/BIO/24/000036	Trastuzumab	For the treatment of HER2-positive metastatic breast cancer	<p>Dosage Form: Powder for concentrate for Solution for Infusion.</p> <p>Strength: 150mg/vial &amp; 420mg/vial</p>

**Annexure 'B'**

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  Strength: 420mg/14mL (30mg/mL)
69	M/s Enzene Biosciences Ltd.	29-04-2024	MF/BIO/24/000046  <b>Note:</b> 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  <b>Note:</b> Due to change of MA holder	Etanercept Injection	Rheumatoid Arthritis (RA) – <ul style="list-style-type: none"> <li>• 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.</li> <li>• Etanercept can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate</li> <li>• Etanercept is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.</li> <li>• 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</li> </ul> <b>Juvenile Idiopathic Arthritis (JIA) –</b> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Treatment of enthesitis-related arthritis in</li> </ul>	Dosage Form: Solution for subcutaneous Injection (single use)  Strength: 50mg/mL & 25mg/0.5mL in PFS and 50mg/mL in PFP

**Annexure 'B'**

					<p>adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.</p> <ul style="list-style-type: none"> <li>• Etanercept has not been studied in children aged less than 2 years.</li> </ul> <p><b>Psoriatic Arthritis (PsA) –</b> 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.</p> <p><b>Axial spondyloarthritis</b> <b>Ankylosing Spondylitis (AS) –</b>Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.</p> <p><b>Nonradiographic Axial Spondyloarthritis (nr-AxSpA) –</b>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).</p> <p><b>Plaque Psoriasis (PsO) –</b>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).</p> <p><b>Pediatric Plaque Psoriasis –</b>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.</p>	
71	M/s Biocon Biologics Limited	30-04-2024	MF/BIO/24/000047 <b>Note:</b> 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