List of new drugs (r-DNA origin) approved for import and marketing in India for the Year 2021						
S. No.	**Name of the firm**	**Date of Permission**	**Permission No.**	**Name of the Drug**	**Indication**	**Dosage Form & Strength**
1	Novo Nordisk India Private Limited	02-03-2021	IMP/BIO/21/000001	Turoctocog Alfa Pegol	Turoctocog alfa pegol [antihemophilic factor (recombinant), glycopegylated-exei] is a recombinant DNA-derived coagulation Factor VIII concentrate indicated for use in adults and children with hemophilia A for: On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes Limitation of Use: Turoctocog alfa pegol is not indicated for the treatment of von Willebrand disease	Turoctocog alfa pegol lyophilised powder for reconstitution into a solution for injection for intravenous use in 5 strengths namely 500 IU/vial, 1000 IU/vial, 1500 IU/vial, 2000 IU/vial and 3000 IU/vial; single dose vial pack for single use administration
2	M/s Novartis Healthcare Private Limited	12-03-2021	IMP/BIO/21/000004	Ofatumumab	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	Ofatumumab 20 mg/0.4 mL Solution for injection in pre-filled syringe
3	Novartis Healthcare Private Limited	26-03-2021	Import 6200/05 dated 26.10.2005, 12-57/05-DC/Novartis/09. Suppl.Changes-1 dated 01.04.2010, 4-16/Novartis/PAC-R-Omalizumab/14-BD dated 22.10.2014, 4-17/Novartis/PAC-R-Omalizumab/15-BD dated 18.05.2015, 4-160/ Novartis/PAC-ROmalizumab/15-BD dated 26.10.2015	Omalizumab	**Additional indication -** Omalizuamb is indicated as an add-on therapy with intranasal corticosteroids (INC) for the treatment of adults (18 years and above) with severe Chronic rhinosinusitis with nasal polyps for whom therapy with INC does not provide adequate disease control	(a) Omalizumab powder and solvent for solution for injection 75 mg & 150 mg single-use vial (b) Omalizumab solution for injection in a pre-filled syringe 75 mg/0.5 mL and 150 mg/1.0 mL single-use pre-filled syringe; for subcutaneous administration only
4	Sanofi-synthelabo (India) Pvt. Ltd.	08-04-2021	IMP-119/2016 dated 02-Aug-2016	Agalsidase Beta	Agalsidase Beta is indicated for long term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry Disease (α-galactosidase A deficiency)	**additional strength** "Agalsidase Beta (r-DNA origin) 5 mg Vial, Powder for Concentrate for Solution for Infusion"
5	Roche Products (India) Pvt. Ltd	03-05-2021	IMP/BIO/21/000017	Casirivimab (r-DNA origin) and Imdevimab (r-DNA origin)	Combination of Casirivimab and Imdevimab indicated for restricted use in emergency situation, for the treatment of mild to moderate corona virus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with laboratory confirmed SARS-COV2 infection and who are at high risk of severe COVID-19 and does not require oxygen.	Casirivimab is a sterile, preservative-free, clear to slightly opalescent, color less to pale yellow solution. Imdevimab is a sterile, preservative-free, clear to slightly opalescent, color less to pale yellow solution with a pH of 6.0. Casirivimab and Imdevimab are each supplied in individual single-dose vials. Casirivimab and Imdevimab is approved at combine dose of 1200 mg (600 mg of each drug) administered by intravenous infusion or subcutaneous route.

6	Amgen Technology Private Limited,	04-05-2021	IMP/BIO/21/000018	Romosozumab	Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture Romosozumab is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.	Romosozumab (r-DNA origin) Injection 90 mg/mL. 105 mg/1.17mL clear to opalescent, colorless to light yellow solution for injection in a single-use prefilled syringe for Subcutaneous use
7	Eli Lilly And Company	26-05-2021	IMP/BIO/21/000025	Bamlanivimab (r-DNA origin) and Etesevimab(r-DNA origin)	Combination of Bamlanivimab and etesevimab indicated for restricted use in emergency situation,IV route for the treatment of mild to moderate corona virus disease 2019 (COVID-19) for injection administration in hospital settings in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with RT-PCR positive results of direct SARS-COV2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization and do not require oxygen.	Bamlanivimab 700mg/20 ml and Etesevimab 700mg/20ml: individual single dose vials.
8	Johnson & Johnson Pvt. Ltd	01-06-2021	IMP/BIO/21/000027	Daratumumab	a) In combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant. b) In combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant. c) For the treatment of patients with multiple myeloma who have received at least one prior therapy. d) For the treatment of patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent.	Daratumumab 1800 mg (120 mg/mL). The product is supplied in vial as a sterile, 120mg/mL liquid for subcutaneous injection. Each vial contains 1800 mg of Daratumumab in a 15mL nominal fill volume and an excess volume of at least 1.3mL. The Drug Product contains no preservatives and is for single use only.
9	Merck Specialities Private Limited	02-06-2021	IMP/BIO/19/000052 (Drug originally approved on 31-Dec-2019	Avelumab	**Additional indication -** 1) Avelumab is indicated as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) whose disease has not progressed with first-line platinum-based induction chemotherapy. 2) Avelumab in combination with axitinib is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC)	Avelumab concentrate for solution for infusion (Intravenous Infusion) 20 mg/ml vial
10	Roche Products (India) Pvt. Ltd	09-06-2021	IMP/BIO/21/000030	Satralizumab	Satralizumab is indicated as monotherapy or in combination with immunosuppressants for the treatment of adult and adolescent patients with neuromyelitis optica spectrum disorders (NMOSD).	Satralizumab Injection 120 mg/ml pre-filled syringe (PFS) with needle safety device (NSD) for subcutaneous use for single dose administration