List of new drugs (r-DNA origin) approved for mannufacture and marketing in India for the Year 2020						
S. No.	**Name of the firm**	**Date of Permission**	**Permission No.**	**Name of the Drug**	**Indication**	**Dosage Form & Strength**
1	Reliance Life Sciences Pvt. Ltd.	21-Feb-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.	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	Reliance Life Sciences Pvt. Ltd.	26-Feb-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	Reliance Life Sciences Pvt. Ltd	30-Mar-2020	MF/BIO/20/000024	Ranibizumab Injection	Indicated for the Neovascular (Wet) Age-Related Macular Degeneration (AMD).	Solution for Injection in vial. Ranibizumab 0.5 mg -10mg/ml (2.3 mg/0.23ml) - Ranibizumab 0.3 mg - 6mg/ml (1.38 mg /0.23 ml) 1. Single Use Vial (Single vial containing of 0.5 mg or o.3 mg Ranibizumab) 2. Combikit
4	Reliance Life Sciences Pvt. Ltd	3-Apr-2020	MF/BIO/20/000026	Ranibizumab bulk drug substance	Not applicable	Ranibizumab bulk drug substance 12 mg/mL to 18 mg/mL
7	USV Private Limited	13-Apr-2020	MF/BIO/20/000030	Pegfilgrastim bulk drug substance	Not applicable	Pegfilgrastim bulk drug substance
5	Biocon Biologics India Limited	21-Sep-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
6	Biocon Biologics India Limited	22-Sep-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