

List of new drugs (r-DNA origin) approved for manufacture and marketing in India for the Year 2021

S. No.	Name of the firm	Date of	Permission No.	Name of the	Indication	Dosage Form & Strength
1	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 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 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 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 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.	Solution for subcutaneous Injection (single use)Pre-filled syringe:(i). 50 mg/mL in Prefilled Syringes(ii). 25 mg /0.5 mL in Pre-filled SyringesPre-filled Pen:(i). 50 mg/mL Pre-filled pen
2	Mylan Pharmaceutical Private Limited	11-Jan-21	Bulk-BIO/03/2021	Etanercept drug substance (r-DNA origin)	NA	Protein Concentration 50 ± 5 mg/mL
3	Cadila Healthcare Limited	12-01-2021	MF/BIO/21/000008	Trastuzumab emtansine bulk	NA	Trastuzumab emtansine (r-DNA origin) Bulk drug substance; (Protein Concentration 18.00 –22.00 mg/mL), in-house specification
4	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 mL Reusable pen with cartridge in blisters
5	Cadila Healthcare Limited	23-Apr-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 subcutaneous)
6	Epygen Biotech Private Limited	21-May-21	MF/BIO/21/000046	Biphasic Isophane Insulin Injection IP	Treatment of Diabetes mellitus	40 IU/ml 10 mL vials
7	Enzene Biosciences Ltd	01-Jul-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).	Romiplostim Injection (r-DNA Origin) 125 mcg/vial, 250 mcg/vial and 500 mcg/vial (Lyophilized powder for solution for injection in single use vial to be used as solution for injection for subcutaneous use after reconstitution)
8	Enzene Biosciences Ltd	01-Jul-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)