

**Status of Registration Certificate (Form 41) of Human Vaccine & Recombinant Products Issued from
01/01/2019 to 31/12/2019**

S. No.	Firm	Name of Formulation	Registration Certificate no & validity
Human Vaccine			
1	M/s Abbott India Ltd Cold Room No. 601, Plot No. K-12, M.I.D.C Taloja, Panvel, Maharashtra, Panvel, Raigad	Inactivated Influenza Vaccine (Surface antigen I P (Quadrivalent) (Influvac Tetra) Injection for intramuscular route of administration (1X 0.5 ml) PFS (For single use)	SVH-2 (Endorsement 1)valid up to 30- April-2021
2	M/s Pfizer Ltd The capital-A wing, 1802, 18 th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra-(E) Mumbai-Zone 4	Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) I.P., 13-valent Multidose Vial I.P. (Prevenar 13)	RC/BIO-000079 valid up to 13-Aug-2022
3	M/s Pusan Bio Research Enterprizes, Chember No. 6 5 th Flr, Cabin No. 2, A. A Cold Storage, D/395, MIDC T.T.C. INDL. Area, Navi Mumbai, KUKSHET Tal. & Dist. Thane Tal-Thurbhe (Thane Zone7), Maharashtra	Rabies Vaccine Human I.P (Vero Cell-Freeze Dried) 0.5ml / Vial, Sterile water for injection I.P., 0.5ml in ampoule	SV-52 valid up to 10-Mar-2022
4	M/s Wockhardt Limited, Bldg No. B GALA No. 1 to 18, Aastha Industrial Park, Plot No.76, Lonad, Bhiwandi - 16(Thane Z5), Maharashtra, Bhiwandi, Thane- 421302(India)	Freeze dried live Attenuated Hepatitis A Vaccine (Biovac A) Lyophilized powder for solution for injection.	SVH-4 valid up to 26-May-2022
5	M/s Sanofi Pasteur India Pvt. Ltd. Room No. 10, First Floor, EL-223, T. T. C. Industrial Area, MIDC, Navi Mumbai, Mahape Tal & Dist. Thane., Mahape, Thane-400710(India)	Adsorbed Diphtheria Tetanus Pertussis (acellular Component) and Poliomyelitis (inactivated) Vaccine I.P [Brand name: Tetraxim] suspension for injection in prefilled syringe.	SV-5(Endorsement No. 1) valid up to 31- Dec-2020

6	M/s GSK Pharmaceuticals Ltd S.No. 14/04, Godown No. 01 & 02, Village Yavai Near water filtration plant, Bhiwandi Dist. Thane Maharashtra Bhiwandi Thane-421302 (India)	Inactivated Influenza Vaccine (Split Virion) I.P suspension for injection for intramuscular route of administration. 0.5ml suspension in prefilled syringe (PFS) with plunger stopper (grey butyl rubber) in the following pack sizes a. 1 PFS + 1 needle [single dose (0.5ml)] b. 1 PFS + 2 needle [single dose (0.5ml)] c. 10 PFS + 10 needle [10X1 dose (0.5ml)]	RC/BIO-000068 valid up to 13-Jun-2022
7	M/s Novo Medi Sciences Pvt, Ltd., Shop No. 2 Suyash Heights, Plot No. 36, Sector-18 Kharghar, tal: Panvel (Raigad), Pin 4210210, India	Live Attenuated Varicella Vaccine, Lyophilized powder when reconstituted to a suspension for subcutaneous Administration	SVH-12 valid up to 27-Aug-2021
8	M/s GSK Pharmaceuticals Ltd southern portion of Ground And First Floor Poonamallee High Road Velappanchavadi, Tamil Nadu Chennai-600077	Pneumococcal Polysaccharide Conjugate Vaccine adsorbed (I.P) (Synflorix) suspension for injection in Vial	SV-15 (Endorsement No. 1) valid up to 31-Dec-2020

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Recombinant Products			
1	M/s Shantha Biotechnics Pvt, Ltd Survey No. 354, Manoharabad, Telangana, Muppireddipalli Village, Medak- 502236 (India)	Insulin Glargine Injection I.P. 100.00 IU/ml solution for injection Cartridges (3 ml)	RC/BIO-000103 valid up to 28-Nov-2022
2	M/s AstraZeneca Pharma India Ltd, Sy. No. 5-2/E, 12 th Mile On Bellary Road Yelahanka, Bangalore, Karnataka, Bangalore, Bangaluru (Bangalore), Rular- 560063 (India)	Durvalumab (r-DNA origin) (Brand Name: Imfinzi) solution for infusion i Each single use vial Contains:-Durvalumab 120mg/2.4 ml ii Each single use vial Contains:-Durvalumab 500mg/10 ml	RC/BIO-000060 valid up to 17-Apr-2022

3	M/s Eli Lilly and Company India Pvt. Ltd., Bldg. No. 14, Gala No. 1 to 4, 1 st Fl., Arihant Comm. Complex, Opp. Koper Bus Stop, Maharashtra, Purana Bhiwandi, Thane - 421302(India)	Insulin Lispro I.P. 100. IU/ml	FF-17(Endorsement no. 1) valid up to 31-Dec-2020
4	M/s Takeda Pharmaceuticals India Pvt, Ltd, Unit No.112, 1 st floor, The Capital plot No. C-70, G Block Bandra Kurla Complex, Bandra (East) Mumbai, Maharashtra, Mumbai, Mumbai city-400051 (India)	Vedolizumab 300mg Powder for concentrate for solution for infusion.	RC/BIO-000102 valid up to 27-Nov-2022
5	M/s Roche Products India Pvt, Ltd , Plot No. 13-A, Paper Box House, Survey No. 78, Hissa No. 1 CTS No. 46/15, Mahakali Road, Andheri (East), Mumbai Maharashtra, Andheri (East),	Atezolizumab Injection 840mg/14ml	FFR-35(Endorsement No. 1) valid up to 16-Nov-2022
6	M/s Pfizer Products India Pvt, Ltd, The Capital-B wing , 1802, 18 th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra-(E) Mumbai-Zone 4	Nonacog Alfa (recombinant coagulation factor IX) 250 IU, 500IU, 1000IU, 2000IU & 3000IU powder and solvent for solution for injection.	RC/BIO-000089 valid up to 23-Sep-2022
7	M/s LG Chem Life Sciences India Pvt, Ltd Basment Commercial SCO No. 321 Sctor -29, Haryana, Gurugram-122001(India)	1. Recombinant Human Erythropoetin Injection I.P. 10000 IU/1 ml 2. Recombinant Human Erythropoetin Injection I.P. 20000 IU/2 ml 3. Recombinant Human Follicle Stimulating Hormone Solution for Injection I.P. 75 IU/0.15 ml 4. Recombinant Human Follicle Stimulating Hormone Solution Solution for Injection I.P. 150 IU/0.30 ml 5. Recombinant Human Follicle Stimulating	SV-13 valid up to 31-Mar-2022

		Hormone Solution for Injection I.P. 225 IU/0.45 ml 6. Recombinant Human Follicle Stimulating Hormone Solution for Injection I.P.300IU/0.60 ml	
8	M/s Novo Nordisk India Pvt, Ltd , Plot No. 32, 47-50, EPIP Area, WhiteField, Karnataka, Bangalore, Bengaluru (Bangalore) urban-560066 (India)	1. Human Growth Hormone Injection(Somatropin)(biosynthetic, R-dna Origin) 5mg/1.5ml in a prefilled Precision Delivery Device to be used with Novo Twist Needles.(Norditropin Nordiflex 5mg/1.5ml) U.S.P., E.P., J.P.3.300mg/ml 2. Human Growth Hormone Injection(Somatropin)(biosynthetic, R-dna Origin) 10mg/1.5ml in a prefilled Precision Delivery Device to be used with Novo Twist Needles.(Norditropin Nordiflex 5mg/1.5ml) U.S.P., E.P., J.P.6.700mg/ml 3. Human Growth Hormone Injection(Somatropin)(biosynthetic, R-dna Origin) 15mg/1.5ml in a prefilled Precision Delivery Device to be used with Novo Twist Needles.(Norditropin Nordiflex 5mg/1.5ml) U.S.P., E.P., J.P.10mg/ml	FF-15 (Endorsement No. 1)valid up to 31-Dec-2020
9	M/s Biocon Ltd , Special Economic Xone, Plot no. 2,3,4 &5 Phase IV, Bommasandra Jigani Link Road, Bommasandra Post, Karnataka, Bengaluru,(Bangalore) Rural-560099	Insulin Glargine (r-DNA origin) Bulk (95 %-105%)	FFR-52 valid up to 28-Feb-2021
10	M/s Ferring Pharmaceuticals Pvt, Ltd Bulding No. B4, Gala No.1 & 2 City link warehousing complex vadape village, Maharastra, Bhiwandi, Thane-421302(India)	Somatropin for injection 4 mg (12 IU)[Somatropin(Recombinant Human Growth Hormone)](Zomacton)	FFR-20 valid up to 30-Apr-2022

11	M/s Johnson & Johnson Pvt, Ltd, Gala No. 3, Bldg. No. B-2, Citylink Warehousing Complex, S. No. 120-121, Mumbai Nashik Highway, Village Vadpe Tal-Bhiwandi, Tal: Bhiwandi-16 (Thane Z5), Pin:421302, India	1. Golimumab (r-DNA Origin)-[Simponi] solution for injection in Pre-filled syringe (ultrasafe) and/or in Autoinjector (Smartject) 2. Recombinant Human Erythropoietin Injection in Pre-filled syringes (Eprex®) of following strengths: • 1,000 IU/0.5 ml • 2,000 IU/0.5ml • 3,000 IU/0.3 ml • 4,000 IU/0.4 ml • 5000 IU/0.5 ml • 6,000 IU / 0.6 ml • 8,000 IU / 0.8 ml • 10,000 IU/1.0 ml • 40,000 IU/1.0 ml 3. Siltuximab powder for concentrate for solution for infusion 100mg & 400mg (r-DNA origin) Sylvant. 4. Infliximab powder for concentrate for solution for infusion 100 mg/vial (r-DNA origin) Remicade. 5. Daratumumab concentrate for solution for infusion 100mg & 400 mg Darzalex.	FF-101 valid up to 01-Jul-2021
12	M/s Eli Lilly and Company India Pvt, Bldg. No. 14 Gala No. 1 to 4 1 st FI Arihant Comm. Complex, Opp Koper Bus Stop, Purana-BHi, Tal Bhiwandi-14(Thane- Zone 5) Pin: 421302	Insulin Glargine I.P. 100 U/ml, 3ml Solution for Injection in Cartridge	FFR-20 valid up to 31-Jan-2021
13	M/s Roche Products India Pvt, Ltd, Plot No. 13-A, Paper Box House, Survey No. 78, Hissa No. 1 CTS No. 46/15, Mahakali Road, Andheri (East), Mumbai Maharashtra, Andheri (East),	Emicizumab Injection(r-DNA Origin) solution for injection (for Subcutaneous administration) 30mg/60mg/105mg/150mg per vial.	RC/BIO-00042 valid up to 03-Dec-2021

14	M/s Novartis Healthcare Pvt, Ltd , Gala No. 1-A & 2-A Bldg. No. 28 Arihant Comp., Kopar , Purana Tal Bhiwandi-14 (Thane Z5), Maharashtra, Thane-421302	Omalizumab Solution for injection in Pre-filled syringe (PFS) 75 mg [Xolair] Omalizumab Solution for injection in Pre-filled syringe (PFS) 150 mg [Xolair]	FFR-40 valid up to 17-Dec-2021
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