

**Status of Registration Certificate (Form 41) of Human Vaccine & Recombinant Products Issued from 01/01/2020
to 30/09/2020**

S. No.	Firm	Name of Formulation	Registration Certificate no & validity
Human Vaccine			
1	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	1.Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) I.P., 13-valent Single dose pre-filled Syringe 2.Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) I.p., 13-valent Single Dose Vial I.P.	RC/BIO-000079 valid up to 13-Aug-2022
2	M/s Techinvention Lifecare Pvt Ltd, 702, Samarpan complex, New Link Road, Chakala, Andheri East, Maharashtra, Mumbai,	Inactivated hepatitis A Vaccine I.P. (Ready to fill) [Strain: HAV (Hepatitis A Virus) TZ84]	RC/BIO-000110 valid up to 31-Jan-2023
3	M/s GlaxoSmithKline Asia Private Limited, North Eastern Side Of The Ground Floor, Building No. 144, Poonamallee High Road,, Tamil Nadu, Velappanchavadi, Chennai- 600077 (India)	1.Human Papillomavirus Vaccine (r-DNA), Ph. Eur. [Brand Name: Cervarix] 2.Rotavirus Vaccine (Live Attenuated, Oral) I.P. [Brand Name: Rotarix]	SV-64 VALID UP TO 11-Dec-2022

4	M/s GLAXOSMITHKLINE PHARMACEUTICALS LIMITED, S.NO. 14/04 , Godown No. 01 & 02, Village Yavai Near Water Filtration Plant, Bhiwandi Dist. Thane, Maharashtra, Bhiwandi, Thane- 421302 (India)	Meningococ cal Groups A, C, W-135 And Y Conjugate Vaccine (MENVEO)	SVH-18 VALID UP TO 24-Aug- 2023
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S. No.	Firm	Name of Formulation	Registration Certificate no & validity
Recombinant Products			
1	M/s Sandoz Pvt, Ltd Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purana, Tal Bhiwandi, Dist, Thane. Bhiwandi (Thane Zone 5) Maharashtra-421302	1. Crizanlizumab: Concentrate for solution for infusion 10mg/mL(100mg/10 mL) [Brand Name-RYVERNA]	RC/BIO-000141valid up to 17- Aug-2023
2	M/s Sanofi-Synthelabo india Private liited, City Link Warehousing Complex, bldg no. 3, Gala no. 6A,S.No. 120- 121 Village Vadpe, Tal- Bhiwandi421302, taluka Bhiwandi-13(Bhiwandi	1. Alglucosidase alfa For injection (r-dna Origin) Lyophilized powder For Concentrate for Solution for Intravenous Infusion 50.000 milligram (mg) 2. Alemfuzumab ((r-dna Origin) Concentrate For solution for infusion in Vial (for Intravenous Use After Dilution) 12.000 milligram (mg)	FFR-31 Valid Up to 27-Dec-2022

	Corporation) ThaneZ5, Maharashtra, Bhiwandi, thane-421302 (india)		
3	M/s Merck Specialties Pvt, Ltd Gala no. 1 to 10 , Bldg no. C-9, Shree Arihant Compound, Ground Floor, Retibunder Road Kalher Bhiwandi, Maharashtra (India)- 421302	1. Chorigonadotropin alfa (r-DNA Human Chorionic gonadotropin Hormone 250mcg/0.5ml 2. Somatropin for injection I.P. Powder and solvent for solution for injection/Somatropin-Recombinat DNA Human growth hormone 8mg injection. 3. Interferon beta-1a Injection I.P./r-human Interferon beta 1a 22 micrograms/0.5ml; 44 micrograms/0.5ml solution for injection in prefilled syringe. 4. Follicle Stimulating Hormone I.P/Follitropine alfa (r-DNA human follicle Stimulating hormone) 450 IU/0.75ml (33mcg/0.75ml).I 1050 IU/1.75ml (77mcg/1.75ml) Powder and solvent for solution for injection. 5. Follicle Stimulting Hormone Injection I.P/follitropin alfa; 300IU/0.5ml (22mcg/0.5ml), 450IU/0.75ml (33mcg/0.75ml), 900IU/1.5ml (66mcg/1.5ml) solution for injection in pre-filledpen. 6. Choriogonadotropin alfa 250mcg/0.5ml Cartridge in a Pre-filled Pen & one Injection needle 7. Interferon beta-1a injection I.P./r-human Interferon beta 1a 22 micrograms/0.5ml; 44 micrograms/0.5ml Solution for injection in prefilled pen. 8. Saizen 5.83mg/ml- somatropin for injection I.P /Hman somatropin Hormone injection (I Cartridge of 1.03 ml containing 6 mg of Somatropin) r-hGH Soltion for injection. 9. Saizen® 8 mg/ml- somatropin for Injection I.P/ Human Somatropin hormone injection (I Cartridge of 1.5 ml containing 12mg of Somatropin) r-hGH Solution for injection. 10. Saizen® 8 mg/ml- somatropin for Injection I.P/ Human Somatropin hormone injection (I Cartridge of 2.5 ml	FFR-13 Valid Up to 06-aug-2023

		Containing 20 mg of Somatropin) r-hGH solution for injection. 11. Rebif- interferon beta-1a injection I.P/r-human interferon beta 1a solution for injection in Cartridge, 66mcg (18MIU)/1.5 ml & 132mcg (36MIU)/ 1.5ml both in multidose cartridge.	
4	M/s Sandoz Pvt, Ltd Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purana, Tal Bhiwandi, Dist, Thane. Bhiwandi (Thane Zone 5) Maharashtra-421302	1. Ranibizumab Solution For injection in pre-filled Syringe 10.000 mg/ml	RC/BIO-000113 Valid up to 16-Feb-2023
5	M/s Bristol-Myers Squibb india pvt Ltd, BLDG. B-4 Gala No. 3B & 4B, CityLink Warehousing Comple Mumabi Nashik highway, Vadape Village, Bhiwandi-16 (Thane Z5), maharashtra, Bhiwandi, Thane-421302 india	1. Nivolumab (Opdyta) 10mg/ml concentrate for solution for infusion 40mg/4ml. (Package:1 Vial). 2. Nivolumab (Opdyta) 10mg/ml concentrate for solution for infusion 40mg/4ml. (1 Vial for patient assistance program).) 3. Nivolumab (Opdyta) 10mg/ml concentrate for solution for infusion 100mg/10ml. (Package:1 Vial) 4. Nivolumab (Opdyta) 10mg/ml concentrate for solution for infusion 100mg/10ml. (1 Vial for patient assistance program).) 5. Ipilimumab Injection, 50 mg/10 ml (5mg/ml), Single use Vial.[Brand Name -Yervoi] 6. Ipilimumab Injection, 50 mg/10 ml (5mg/ml), Single use Vial.{Packed for use for BMS Patient Assistance Program}][Brand Name-Yervoi]	RC/BIO-000107 Valid Up to 31-Dec-2022
6	M/s Roche Products (India) Private Limited, Plot No. 13-A, Paper Box House, Survey No. 78, Hissa No. 1 CTS	1. Atezolizumab Injection 840mg/14ml Concentrate for Solution for infusion in vial (Intravenous (IV) infusion)	RC/BIO-000108 VALID UP TO 29-Jan-2023

	No. 46/15, Mahakali Road, Andheri (East), Mumbai, Maharashtra, Andheri East, Mumbai Suburban- 400093 (India)		
7	M/s Roche Products (India) Private Limited, 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, Mumbai Suburban- 400093 (India)	1.Tocilizumab (r-DNA origin) Injection Solution for Injection for subcutaneous use	RC/BIO-000109 VALID UP TO 29-Jan-2023
8	M/s Sanofi-Synthelabo India Private Limited, City Link Warehousing Complex,Bldg No. 3, Gala No.6A,S.No.120-121,Village Vadpe, Tal-Bhiwandi421302,Taluka Bhiwandi-13(Bhiwandi Corporation)ThaneZ5, Maharashtra, Bhiwandi, Thane- 421302 (India)	Thyrotropin Alfa (Thyrogen) Lyophilized Powder for solution for injection (For intramuscular use only)	FF-399 VALID UP TO 27-Dec-2022
9	M/s Dr. Reddys Laboratories Limited , Global Distribution Centre Survey No. 41, Bachupally (V), Bachupally (M), Telangana, Hyderabad,	1. Evolocumab Solution for Injection 140mg/ml (r-DNA origin)(Brand name: REPATHA) 2. Denosumab Injection (r-DNA origin)(Brand name: PROLIA) 3. Panitumumab Concentrate for Solution for Infusion (r-DNA origin) (Brand name: VECTIBIX) 4. Denosumab Injection (r-DNA origin)(Brand	FFR-48 VALID UP TO 26-Jul-2023

	Medchal– Malkajigiri500090 (India)	name: XGEVA)	
10	M/s Pfizer Products India Private Limited , The Capital- B Wing, 1802, 18th Floor Plot No. C-70 G Block, Bandra Kurla Complex, Bandra (E), Maharashtra, Mumbai City , Mumbai City400051 (India)	1. Recombinant Somatropin for Injection I.P. (Go-Quick) 5.3 milligram 2. Recombinant Somatropin for Injection I.P. (Go-Quick) 12 milligram 3. Recombinant Somatropin for Injection I.P. (Genotropin) 5.3 milligram 4. Recombinant Somatropin for Injection I.P. (Genotropin) 12 milligram	FF-362 VALID UP TO 31-Mar-2023
11	M/s Pfizer Products India Private Limited , The Capital- B Wing, 1802, 18th Floor Plot No. C-70 G Block, Bandra Kurla Complex, Bandra (E), Maharashtra, Mumbai City , Mumbai City- 400051 (India)	1. Inotuzumab Ozagamicin (r-DNA origin) Powder for concentrate for solution for infusion 1 mg	RC/BIO-000122 VALID UP TO 13-May-2023
12	M/s Biocad India Private Limited, No 268/A, 9th A Main Road Jaynagar 3rd Block , Karnataka, Bengaluru, Bengaluru (Bangalore) Rural- 560011 (India)	1. Infliximab 100 mg powder for concentrate for solution for infusion	FF- 727 VALID UP TO 30-Jun-2021
13	M/s Roche Products (India) Private Limited, Plot No. 13-A, Paper Box House, Survey No. 78, Hissa No. 1 CTS No. 46/15, Mahakali	1. Tocilizumab Injection (Actemra)	RC/BIO-000125 VALID UP TO 02-Jun-2023

	Road, Andheri (East), Mumbai, Maharashtra, Andheri East, Mumbai Suburban- 400093 (India)		
14	M/s Pfizer Limited, The Capital-A Wing, 1802, 18th Floor, Plot No. C- 70, G Block, Bandra Kurla Complex, Bandra -(E), Mumbai-Zone4, Maharashtra, Bandra Kurla Complex Bandra East, Mumbai City- 400051 (India)	1. Etanercept Solution For Injection 25mg in Pre-filled Syringe (Brand name: Enbrel) 25.000 milligram (mg) 2. Etanercept Solution For Injection 50mg in Pre-filled Pen (Brand name: Enbrel) 50.000 milligram (mg)	RC/BIO-000079 VALID UP TO 13-Aug-2022
15	M/s Sun Pharmaceutical Industries Limited, Bldg No. C, Gala No-5,6,7, Kasturi Complex Anjur Road, Rehnal Village, Bhiwandi, Maharashtra, Thane, Thane421308 (India)	1. Somatropin for Injection I.P.(Recombinant Human Growth Hormone for Injection) (Brand name: Headon)) 4 IU (1.33 mg) and 10 IU (4.0mg)	FFR-7 VALID UP TO 27-Mar- 2023
16	M/s Sandoz Private Limited, Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purna. Tal. Bhiwandi, Dist. Thane. Bhiwandi (Thane Zone5)., Maharashtra, Bhiwandi, Thane- 421302 (India)	1. Brolocizumab solution for injection 120 mg/mL (r-DNA origin) Solution for Injection (1 Vial + 1 filter needle)	RC/BIO-000133 VALID UP TO 12-Jul-2023
17	M/s Sandoz Private	1. Erenumab Solution for Injection (Brand name: Suviray)	RC/BIO-000142 VALID UP TO

	Limited, Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purna. Tal. Bhiwandi, Dist. Thane. Bhiwandi (Thane Zone5)., Maharashtra, Bhiwandi, Thane- 421302 (India)	70.00 mg/ml	17-Aug-2023
18	M/s Merck Specialities Pvt Ltd, Plot No. D-116, MIDC, Bldg No 2, 1st Floor, Thane Belapur Road, Shirvane, Maharashtra, Nerul Navi Mumbai, Thane- 400706 (India)	1. Avelumab 20mg/ml Concentrate For Solution for Infusion 200.000 mg/10mL	FFR-12 VALID UP TO 31-MAY- 2023
19	M/s Sanofi-Synthelabo India Private Limited, City Link Warehousing Complex,Bldg No. 3, Gala No.6A,S.No.120- 121,Village Vadpe, Tal- Bhiwandi421302,Taluka Bhiwandi-13(Bhiwandi Corporation)ThaneZ5, Maharashtra, Bhiwandi, Thane- 421302 (India)	1. Laronidase (Aldurazyme) 2.900 mg/5ml Solution for injection	FFR-26 VALID UP TO 08-Jan- 2023