

Status of Import Licenses (Form 10) 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 Limited, The Capital-A Wing, 1802, 18th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra - (E), Mumbai-Zone4, Bandra Kurla Complex Bandra East, Maharashtra (India) - 400051	1. Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) I.p., 13- valent Single Dose Vial I.P. (Prevenar 13)	IL/BIO-000087- RC/BIO-000079 valid till 13-Aug-2022
2	M/s GlaxoSmithKline Pharmaceuticals Limited,, Southern Portion Of Ground And First Floor, No. 144, Poonamallee High Road, Velappanchavadi, Tamil Nadu (India) - 600077	1. Human Papillomavirus Vaccine (r-DNA), Ph. Eur. [Brand Name: Cervarix] 2. Rotavirus Vaccine (Live Attenuated, Oral) I.P. [Brand Name: Rotarix]	SV-64-11 valid till 11-Dec-2022
3	M/s TECHINVENTION LIFECARE PVT LTD, 1004 THE SUMMIT BUSSINESS PARK OFF WEH METRO STATION ANDHERI KURLA ROAD ANDHERI EAST, MUMBAI, Maharashtra	1. Inactivated Hepatitis A Vaccine I.P. (Ready to fill) [Strain: HAV (Hepatitis A virus) TZ84]	IL/BIO-000121 - RC/BIO-000110 valid till 31-Jan-2023

	(India) - 400093		
4	M/s GLAXOSMITHKLINE PHARMACEUTICALS LIMITED, S.NO. 14/04 , Godown No. 01 & 02, Village Yavai Near Water Filtration Plant, Bhiwandi Dist. Thane, Bhiwandi, Maharashtra (India) - 421302	1. Meningococ cal Groups A, C, W135 And Y Conjugate Vaccine (MENVEO)	SVH-18-145 valid till 24-Aug-2023

S. No.	Firm	Name of Formulation	Import License 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. Ranibizumab 10mg/ml (r-DNA origin)	IL/BIO-000114-RC/BIO-000113 valid up to 16-Feb-2023
2.	M/s Eli Lilly And Company (India) pvt ltd, Bldg. no. 14, Gala no. 1 to 4, 1 st F1., arihant comm.. Complex, Opp. Koper	1. Insulin lispro I.P. (Humalog Junior KwikPen)	FF-17-26 Valid up to 31-Dec-2020

	Bus Stop purna bhiwandi, Maharashtra (India)- 421302		
3	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, Andheri East, Maharashtra (India) - 400093	1. Tocilizumab (r-DNA origin) Injection Solution for Injection for subcutaneous use	IL/BIO-000111 - RC/BIO-000109 valid till 29-Jan-2023
4	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, Andheri East, Maharashtra (India) - 400093	1. Atezolizumab Injection 840mg/14ml 4 Concentrate for Solution for infusion in vial (Intravenous (IV) infusion)	IL/BIO-000112 - RC/BIO-000108 valid till 29-Jan-2023
5	M/s Sandoz Private Limited, Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purna. Tal. Bhiwandi, Dist. Thane. Bhiwandi (Thane Zone5)., Bhiwandi, Maharashtra (India) -	1. Ranibizumab solution for injection in vial 10mg/ml + filter needle (Accentrix) 10 mg/ml	IL/BIO-000096-FF-401 valid till 31-Oct-2021

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6	M/s Sanofi-Synthelabo India Private Limited, City Link Warehousing Complex, Bldg No. 3, Gala No.6A, S.No.120-121, Village Vadpe, Tal-Bhiwandi 421302 (Bhiwandi Corporation) Thane Z5, Bhiwandi, Maharashtra (India) - 421302	1. Thyrotropin Alfa (Thyrogen) Lyophilized Powder for solution for injection (For intramuscular use only). 2. Agalsidase beta powder for concentrate for solution for infusion (Fabrazyme) Intravenous infusion	FF-399-9177 valid till 27-Dec-2022
7	M/s Dr. Reddys Laboratories Limited, Global Distribution Centre Survey No. 41, Bachupally (V), Bachupally (M), Hyderabad, Telangana (India) - 500090	1. Evolocumab Solution for Injection 140mg/ml (r-DNA origin) (Brand name: REPATHA) Solution for Injection. 2. Denosumab Injection (r-DNA origin) (Brand name: PROLIA) Solution for subcutaneous Injection. 3. Panitumumab Concentrate for Solution for Infusion (r-DNA origin) (Brand name: VECTIBIX) Concentrate for Solution for Infusion. 4. Denosumab Injection (r-DNA origin) (Brand name: XGEVA) Solution for subcutaneous Injection.	FFR-48-51 valid till 26-Jul-2023
8	M/s BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED, BLDG. B-4, GALA NO. 3B & 4B, CITYLINK WAREHOUSING COMPLEX MUMBAI NASHIK HIGHWAY, VADAPE VILLAGE, BHIWANDI - 16 (THANE Z5), BHIWANDI,	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 /10 ml. (Package: 1 Vial) 4. Nivolumab (Opdyta) 10mg/ml concentrate for solution for Infusion 100mg /10 ml (1 Vial for patient assistance program).	IL/BIO-000120 - RC/BIO-000107 valid till 31-Dec-2022

	Maharashtra (India) - 421302		
9	M/s BRISTOL-MYERS SQUIBB INDIA PRIVATE LIMITED, BLDG. B-4, GALA NO. 3B & 4B, CITYLINK WAREHOUSING COMPLEX MUMBAI NASHIK HIGHWAY, VADAPE VILLAGE, BHIWANDI - 16 (THANE Z5), BHIWANDI, Maharashtra (India) - 421302	1. Ipilimumab Injection, 50 mg/10 ml (5mg/ml), Single use Vial.[Brand Name -Yervoi] 2. Ipilimumab Injection, 50 mg/10 ml (5mg/ml), Single use Vial.{Packed for use for BMS Patient Assistance Program}][Brand Name-Yervoi]	IL/BIO-000123 - RC/BIO-000107 valid till 31-Dec-2022
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), Mumbai City , Maharashtra (India) - 400051	1. Inotuzumab Ozogamicin Powder For Concentrate For Solution For Infusion (Inonza)	IL/BIO-000124 - RC/BIO-000122 valid till 13-May-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), Mumbai City , Maharashtra (India) - 400051	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-362-115 valid till 31-Mar-2023

12	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, Andheri East, Maharashtra (India) - 400093	1. Tocilizumab Injection (Actemra)	IL/BIO-000127 - RC/BIO-000125 valid till 02-Jun-2023
13	M/s Sanofi Healthcare India Private Limited, Insulin Plant, Sy. No. 354, Muppireddipalli Village, Manoharabad Mandal, Telangana (India) - 502236	1. Insulin Glargine Injection I.P. 100.00 IU/ml Solution for injection Cartridges (3mL)	IL/BIO-000128 - RC/BIO-000103 valid till 28-Nov-2022
14	M/s Merck Specialities Pvt. Ltd., GALA NO. 1 TO 10, BLDG NO. C-9, SHREE ARIHANT COMPOUND, GROUND FLOOR, RETIBUNDER ROAD, KALHER, BHIWANDI, Maharashtra (India) - 421302	1. Cetuximab Injection (ERBITUX) Injection (solution for infusion)	IL/BIO-000129 - FF-373 valid till 25-May-2023
15	M/s Merck Specialities Pvt. Ltd., GALA NO. 1 TO 10, BLDG NO. C-9, SHREE ARIHANT COMPOUND, GROUND	1. Follicle Stimulating Hormone I.P. 75 IU (5.5 mcg)/ Follitropin alpha-Recombinant DNA Follicle Stimulating Hormone 75 IU (5.5 mcg) Injection (GONAL-f) 2. Recombinant Human Luteinising Hormone/Lutropin Alfa 75 IU (LUVERIS)	IL/BIO-000130- FFR-12 valid till 31-May-2023

	FLOOR, RETIBUNDER ROAD, KALHER, BHIWANDI, Maharashtra (India) - 421302		
16	M/s Pfizer Limited, The Capital-A Wing, 1802, 18th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra -(E), Mumbai-Zone4, Bandra Kurla Complex Bandra East, Maharashtra (India) - 400051	1. Etanercept Solution For Injection 25mg in Pre-filled Syringe (Brand name: Enbrel) 2. Etanercept Solution For Injection 50mg in Pre-filled Pen (Brand name: Enbrel)	IL/BIO-000087- RC/BIO-000079 valid till 13-Aug-2022
20	M/s Sun Pharmaceutical Industries Limited, Bldg No. C, Gala No-5,6,7, Kasturi Complex Anjur Road, Rehnal Village, Bhiwandi, Thane, Maharashtra (India) - 421308	1. Somatropin for Injection I.P.(Recombinant Human Growth Hormone for Injection) (Brand name: Headon)	FFR-7-10 valid till 27-Mar-2023
21	M/s Sandoz Private Limited, Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purna. Tal. Bhiwandi, Dist. Thane. Bhiwandi (Thane Zone5)., Bhiwandi, Maharashtra (India) -	1. Brolucizumab solution for injection 120 mg/mL (r-DNA origin)[PAGENAX] Solution for Injection (1 Vial + 1 filter needle)	IL/BIO-000136 - RC/BIO-000133 valid till 12-Jul-2023

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22	M/s Roche Products (India) Private Limited, C/O.Parekh Integrated Services Pvt Ltd, Room No. 5, 2nd Floor, Warehouse No.6, Bgr Logistics Park, Nh-3, Zone 5, Bhiwandi, Maharashtra (India) - 421302	1. Epoetin beta Injection I.P. [2000 IU and 5000 IU Pre-filled Syringes along with needle] (Brand name: NeoRecormon)	IL/BIO-000140 - FFR-18 valid till 29-Oct-2021
23	M/s Sandoz Private Limited, Gala No. 11, Bldg. No. 27, Arihant Complex Kopar Bus Stop Purna. Tal. Bhiwandi, Dist. Thane. Bhiwandi (Thane Zone5)., Bhiwandi, Maharashtra (India) - 421302	1. Crizanlizumab Concentrate for solution for infusion 10 mg/mL (100 mg/10 mL)[Brand Name-RYVERNA] Concentrate for solution for infusion	IL/BIO-000143 - RC/BIO-000141 valid till 17-Aug-2023
24	M/s Roche Products (India) Private Limited, C/O.Parekh Integrated Services Pvt Ltd, Room No. 5, 2nd Floor, Warehouse No.6, Bgr Logistics Park, NH-3, Zone 5, Bhiwandi, Maharashtra (India) - 421302	1. Tocilizumab (r-DNA origin) Injection	IL/BIO-000146 - RC/BIO-000109 valid till 29-Jan-2023
25	M/s Roche Products (India) Private Limited,	1. Tocilizumab Injection (Actemra)	IL/BIO-000148 - RC/BIO-000125 valid till 02-Jun-2023

	C/O.Parekh Integrated Services Pvt Ltd, Room No. 5, 2nd Floor, Warehouse No.6, Bgr Logistics Park, NH-3, Zone 5, Bhiwandi, Maharashtra (India) - 421302		
26	M/s Roche Products (India) Private Limited, C/O.Parekh Integrated Services Pvt Ltd, Room No. 5, 2nd Floor, Warehouse No.6, Bgr Logistics Park, NH-3, Zone 5, Bhiwandi, Maharashtra (India) - 421302	1. Atezolizumab Injection 840mg/14ml 4. Concentrate for Solution for infusion in vial (Intravenous (IV) infusion)	IL/BIO-000147 - RC/BIO-000108 valid till 29-Jan-2023
27	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, Bhiwandi, Maharashtra (India) - 421302	1. Alglucosidase alfa for injection (r-DNA Origin) (Brand Name: Myozyme) Lyophilized powder for Concentrate for Solution for Intravenous Infusion. 2. Alemtuzumab (r-DNA Origin) Lemtrada® Concentrate for solution for Infusion in vial (for Intravenous use after dilution	FFR-31-26 valid till 27-Dec-2022
28	M/s Sandoz Private Limited, Gala No. 11, Bldg. No. 27, Arihant	1. Erenumab Solution for Injection (Brand name: Suviray)	IL/BIO-000149 - RC/BIO-000142 valid till 17-Aug-2023

	Complex Kopar Bus Stop Purna. Tal. Bhiwandi, Dist. Thane. Bhiwandi (Thane Zone5)., Bhiwandi, Maharashtra (India) - 421302		
29	M/s Merck Specialities Pvt. Ltd., GALA NO. 1 TO 10, BLDG NO. C-9, SHREE ARIHANT COMPOUND, GROUND FLOOR, RETIBUNDER ROAD, KALHER, BHIWANDI, Maharashtra (India) - 421302	1. OVITRELLE - Choriogonadotropin alfa (r-DNA Human Chorionic gonadotropin Hormone 250mcg/0.5ml) Solution for injection in a Pre-filled syringe. 2. SAIZEN®8mg ClickEasy - Somatropin for Injection I.P. Powder and solvent for solution for injection /Somatropin-Recombinant DNA Human Growth Hormone 8 mg Injection Powder and solvent for solution for injection. 3. Rebif- 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 Solution for injection in prefilled syringe. 4. GONAL-f -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 forinjection. Powder and solvent for solution for injection. 5. GONAL-f Follicle Stimulating Hormone Injection I.P/Follitropin Alfa; 300IU/0.5ml (22mcg/0.5ml), 450IU/0.75ml (33mcg/0.75 ml), 900IU/1.5ml (66mcg/1.5ml) Solutionfor injection in pre-filledpen Solution for Subcutaneous injection. 6. Choriogonadotropin alfa 250mcg/0.5ml Cartridge in a Pre-filled Pen & one Injection needle. 7. Rebif- 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® 5.83 mg/ml- Somatropin for Injection I.P /Human	IL/BIO-000151- FFR-13 valid till 06-Aug-2023

		Somatropin Hormone Injection(I Cartridge of 1.03 ml containing 6 mg of Somatropin) r-hGH Solution for Injection. 9. Saizen® 8 mg/ml-Somatropin for Injection I.P/Human Somatropin Hormone Injection (I Cartridge of 1.5 ml containing 12 mg 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 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 ,66 mcg (18MIU)/l.5 ml & 132mcg (36MIU)/ 1.5ml. both in multidose cartridge	
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