

Annexure-I(b)

Details of Manufacturing Permissions of Human Vaccines

Year 2024					
S.no	Name of Firm	Name of Vaccine	Composition	Indication	Permission No. & Date
1	M/s Bharat Biotech International Ltd, Genome Valley, Shameerpet, Hyderabad, India - 500078.	Rotavirus Vaccine (Live Attenuated, Oral) I.P (ROTAVAC 5D)" vaccine without antibiotics.	Each dose of 0.5 mL (5 drops) contains: Ingredients Vero cell derived Rotavirus 116E Bulk, Live Attenuated : NLT 10 ^{5.00} FFU Sucrose : 0.25 gms Trehalose : 2.5 mg Lactalbumin hydrolysate (LAH) : 2.5 mg Human Albumin : 0.35% Potassium Di hydrogen orthophosphate/ Potassium phosphate monobasic anhydrous : 1.65 mg Dipotassium Hydrogen orthophosphate/ Potassium phosphate dibasic anhydrous : 10 mg Tri Sodium Citrate Dihydrate : 7.75 mg Water for Injection : q.s	Active Immunization of infants from the age of 6-8 weeks for prevention of gastroenteritis due to rotavirus infection.	MF/BIO/24/000028 dated 08-March-2024

2	M/s Bharat Biotech International Ltd, Genome Valley, Shameerpet, Hyderabad, India - 500078.	Cholera Vaccine (Inactivated, Oral), V. cholerae (O1 El Tor Hikojima Serotype recombinant strain) formaldehyde inactivated whole Cell, Phosphate Buffered Saline	Each dose of 1.5 mL contains: Name of the ingredients Active Ingredient: V. cholerae (O1 E1 Tor Hikojima Serotype recombinant strain) formaldehyde inactivated whole cell : $\geq 900 \mu\text{g}$ of LPS Inactive Ingredient: Phosphate buffered saline : q.s. to 1.5 ml	For active immunization against Diarrhoeal infection caused by Vibrio cholerae to the children, adolescents and adults aged 1 year and above with two doses on Day 0 and Day 14.	MF/BIO/24/000043 dated 16-April-2024
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3	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028	Measles Vaccine, Live Attenuated (Freeze-Dried)	Each dose 0.5 ml (on reconstitution) contains: Name of ingredients Measles virus I.P.(Edmonston strain) : NLT 1,000 CCID₅₀ Name of Inactive ingredients Partially Hydrolyzed Gelatin I.P./B.P./Ph.Eur./In-House : 1.250 mg Sorbitol I.P./B.P./Ph Eur. : 2.500 mg L-Histidine B.P./Ph Eur. : 0.105 mg L-Alanine B.P./Ph Eur. : 0.050 mg Tricine In-House : 0.150 mg L-Arginine Hydrochloride B.P./Ph Eur : 0.800 mg Lactalbumin Hydrolysate In-House : 0.175 mg Minimum Essential Medium (MEM) In House : Base (q.s.) Diluent: Sterile Water for Injection IP/BP : 0.5 ml	For active immunization of all susceptible children against measles at 9 months of age.	MF/BIO/24/000045 dated 25-April-2024
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4	M/s Zydus Lifesciences Limited, Plot , Survey No. 23, 25/P, 37, 40/P, 42 to 47,49 & 50, Sarkhej-Bavla N.H. No. 8A, Opp. Ramdev Masala, Village – Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) - 382213,	Measles and Rubella Vaccine (Live) I.P. (Freeze Dried)- Multi Dose vial (2.5ml - 5 dose).	Each dose of 0.5 mL after reconstitution contains: Active Ingredients: Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells) : NLT 1000 CCID ₅₀ Live Attenuated Rubella Virus (RA 27/3 strain)(Propagated on Human Diploid Cells) : NLT 1000 CCID ₅₀ Inactive Ingredients: Gelatin I.P./ Ph.Eur. : 3.92 mg D-Sorbitol I.P./ Ph.Eur. : 7.84 mg D-Lactose monohydrate I.P./ Ph.Eur. : 4.70 mg Lactalbumin Hydrolysate In-house : 0.54 mg Calcium gluconate I.P./ Ph.Eur. : 2.24 mg L-Alanine Ph.Eur. : 0.14 mg L-Histidine Ph.Eur. : 0.32 mg Tricine In-house : 0.46 mg Diluent for reconstitution: Sterile Water for injections I.P.(Glass ampoule for 5 dose	For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously	MF/BIO/24/000052, Date: 16-05-2024
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5	M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028	Measles and Rubella Vaccine (Live Attenuated)(Freeze-Dried), (10 Dose) (0.5ml/Vial)	Each 0.5 ml/vial (10 dose) contains: Active Ingredients Live attenuated Measles virus (Edmonston-Zagreb strain) ## : NLT 1000 CCID⁵⁰ / Dose Live attenuated Rubella virus (WISTAR RA 27/3 strain) propagated on human diploid cells : NLT 1000 CCID⁵⁰ / Dose Inactive Ingredients Partially Hydrolyzed Gelatin : 2.5% Sorbitol : 5.0% L-Histidine : 0.21% L-Alanine : 0.1% Tricine : 0.3% L-Arginine Hydrochloride : 1.60% Lactalbumin Hydrolysate : 0.35% Minimum Essential Medium Base : (q.s.)	For active immunization against Measles and Rubella in infants, children, adolescents of age up to 10 years.	MF/BIO/24/000055 dated 20-May-2024
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6	M /s. Serum Institute of India Pvt. Ltd., S. No. 105 110, Manjari BK, Tal Haveli, Pune 412307, Maharashtra (India)	Covid-19 Vaccine, Adjuvanted 2023-24 Formula [SARSCoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB 1.5 variant] (COVOVAX)	Each dose of 0.5ml of vaccine contains: Ingredients SARS-CoV-2 rS* : 5 µg Matrix-M1 (Matrix A & Matrix C) : 50 µg Sodium Phosphate Dibasic Heptahydrate : 2.465 mg Sodium Phosphate Monohydrate Monobasic : 0.444 mg Sodium Chloride : 8.766 mg Polysorbate 80 : 0.050 mg Water for Injection : q.s. to 0.5 ml *produced in baculovirus-infected Spodoptera frugiperda (SF9) insect cells	Vaccine is indicated for active immunization to prevent COVID – 19 disease (a) in individuals of ≥ 12 to < 18 years of age as primary series of two doses (0.5mL each) 3 weeks apart (b) as single precautionary dose in individuals of ≥ 18 years of age, who have received primary series of vaccinations for restricted use in emergency situation.	BIO/MA/23/000137, dated; 06-06-2024
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7	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N.H.No. 8A, Opp. Ramdev Masala, Village – Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) – 382213.	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) - Multi dose Vial (5.0 ml - 10 dose).	Each dose of 0.5 ml after reconstitution contains: Ingredients: Active Ingredients Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells) : NLT 1000 CCID ₅₀ Live Attenuated Mumps Virus (Hoshino Strain) (Propagated on Chick Fibroblast Cells) : NLT 5000 CCID ₅₀ Live Attenuated Rubella Virus (RA 27/3 strain)(Propagated on Human Diploid Cells) : NLT 1000 CCID ₅₀ Inactive Ingredients: Gelatin : 2.94 mg D-Sorbitol : 5.88 mg Lactose monohydrate : 3.53 mg Lactalbumin Hydrolysate : 0.41 mg Calcium gluconate monohydrate : 1.68 mg L-Alanine : 0.10 mg L-Histidine : 0.24 mg Tricine : 0.35 mg	It is indicated for prevention of Measles, Mumps and Rubella virus infections.	MF/BIO/24/000069, Date: 25-06-2024
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8	M/s Human Biologicals Institute, Sy. No. 281-284 & 321, Biotech Park Phase-3, Karkapatla Village, Mulugu Mandal, Medak District, Telangana-502281.	Rabies Vaccine	Ingredients Inactivated Rabies antigen derived from Rabies virus (L.Pasteur 2061/Vero Strain propagated in vero cells) : ≥ 2.5 IU per vial Maltose monohydrate : 4.5% w/v Human Albumin 20% : 3.5% w/v Thiomersal : $\leq 0.015\%$ w/v Sterile Diluent : 0.9% w/v Sodium Chloride solution	Pre-exposure & Post-exposure prophylaxis against Rabies Infection.	20-08-2024
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9	M/s Sapigen Biologix Private Limited, (Subsidiary of M/s Bharat Biotech International Limited) Plot no- B1/24 and ITBT 1/7, Daspur road, Andharua, Khordha, Bhubaneswar- 751003, Odisha (India)	Rotavirus Vaccine (Live Attenuated, (Oral)	Each USP Type 1 flint glass Vial (0.5 ml/ 1dose) of Oral Rotavirus Vaccine (ORV) 116E contains: Ingredients Rotavirus 116E Bulk, Live : NLT 10 ^{5.0} FFU/0.5mL Potassium phosphate monobasic : 0.258mg Potassium phosphate dibasic : 0.625mg Sucrose : 37.31mg Potassium L-glutamate, monohydrate : 1.0mg Neomycin sulphate : 15ug Kanaraycin sulphate : 15ug Dulbecco's Modified Eagle's Medium (DMEM) : 4.4mg Water for Injection : qs	Active Immunization of infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection.	11-09-2024
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10	M/s Sapigen Biologix Private Limited, (Subsidiary of M/s Bharat Biotech International Limited) Plot no- B1/24 and ITBT 1/7, Daspur road, Andharua, Khordha, Bhubaneswar- 751003, Odisha (India)	Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral)	Each dose of two drops (0.1ml) of Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral) contains: Quantity per dose of 0.1 ml (20 doses/vial) Active Ingredients Poliovirus Type 1 (Sabin Strain) - Not less than $10^{6.0}$ CCID ₅₀ Poliovirus Type 3 (Sabin Strain) - Not less than $10^{5.8}$ CCID ₅₀ Inactive ingredients MgCl ₂ ·6H ₂ O - 20.33mg Tween 80 - 10mcg Kanamycin acid sulphate - 15mcg Neomycin sulphate - 15mcg Water for Injection - q.s. to 0.1 mL.	For active Immunization against Type 1 & Type 3 Poliomyelitis infection in Children from 0 to 5 years of age.	16-10-2024
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11	M/s Seasons Biologicals Private Limited, 302 Skill Spectrum 3-6-3639 Liberty JN, Himayatnagar, Hyderabad, Telangana-500029, India.	Tetanus Vaccine (Adsorbed) I.P	Each dose of 0.5 ml contains: Ingredients Tetanus Toxoid (Strain : Clostridium Tetani Harvard strain 49205) : ≥ 5.00 Lf Aluminium Phosphate Gel (as Al+++) : ≤ 1.25 mg Thiomersal : 0.01% w/v Normal Saline : Q.S.	For active immunization against tetanus infection when administered as single dose of 0.5 ml in the age group of 10 to 45 years	MF/BIO/22/000068, Date: 16-10-2024
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12	M/s Zydus Lifesciences Limited, Survey No. 417, 419 and 420, Sarkhej Bavla N. H. No. 8A, Village: Moraiya, Tal.: Sanand, Dist.: Ahmedabad 382210, State: Gujarat, India	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECVPM]	1 vial of Lyophilized Powder contains: Inactivated rabies virus (Pitman Moore Strain) Potency ≥ 2.5 IU Virus is propagated in chick embryo fibroblast cell culture and Inactivated by β -propiolactone. 1 ml sterile Water for Injection IP.	For active Immunization against rabies;- (1) For Intramuscular administration, use 1 full dose(1ml) for pre & Post exposure prophylaxis (2) For Intradermal administration, use 0.1 ml per ID site for Post exposure prophylaxis	02-12-2024
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13	M/s Panacea Biotech Ltd, A-27, B-1 Extension Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) -110044	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents IP	Each dose of 0.5 ml contains: Active Ingredients: Diphtheria Toxoid : NLT 2 IU Tetanus Toxoid : NLT 20 IU Inactive Ingredients: Aluminium content (Al ³⁺) (as Aluminium phosphate gel) : NMT 1.25 mg 2-Phenoxyethanol : 2.5 mg Physiological Saline : q.s to 0.5 ml	Active immunization against Tetanus and Diphtheria in children aged 10 years or older, as well as in adolescents and adults	02-12-2024
14	M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej- Bavla N. H. No. 8A, Opp. Ramdev Masala, Village - Changodar, Taluka: Sanand, Dist. Ahmedabad, Gujarat (India) – 382213	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECVPM]	1 vial of Lyophilized Powder contains: Inactivated rabies virus (Pitman Moore Strain) Potency ≥ 2.5 IU Virus is propagated in chick embryo fibroblast cell culture and Inactivated by β -propiolactone. 1 ml sterile Water for Injection IP.	For active Immunization against rabies;- (1) For Intramuscular administration, use 1 full dose(1ml) for pre & Post exposure prophylaxis (2) For Intradermal administration, use 0.1 ml per ID site for Post exposure prophylaxis	26-12-2024