

Annexure-IV(a):

Details of applications of manufacturing license of vaccines in Form 28D/28DA and its regulatory status (Approved/Withdrawn) -Jan. 2025 to DEC. 2025

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)
1.	M/s Zydus Lifescience Limited, Plot No. 23, 25/P, 37, 40/P 42 to 47, 49 & 50 Sarkhej-Bavla N. h. No. 8A, Opp. Ramdev Masala Village: Changodar, Tal. Sanand, Dist. Ahmedabad -382 213, State Gujarat	1. Formulated Bulk of Inactivated Influenza Vaccine (Split Virion) Tetravalent I.P. (Ready to fill) (Domestic) 2. Formulated Bulk of Inactivated Influenza Vaccine (Split Virion) Tetravalent B.P. (Ready to fill) (Export)	09.01.2025	Nil
2.	M/s Zydus Lifescience Limited, Plot No. 23, 25/P, 37, 40/P 42 to 47, 49 50 Sarkhej-Bavla N. h. No. 8A, Opp. Ramdev Masala Village: Changodar, Tal. Sanand, Dist. Ahmedabad -382 213, State Gujarat	1. Inactivated Influenza Vaccine (Split Virion) I.P. Trivalent 0.5 ml (single Dose) vials (Domestic) 2. Inactivated Influenza Vaccine (Split Virion) I.P. Trivalent 0.5 ml (single Dose) vials (Domestic) Vaccine combipack	09.01.2025	Nil
3.	M/s Panacea Biotech Ltd. Malpur, Baddi, Distt. Solan (H.P.)-173205 India.	Bivalent Poliomyelitis Vaccine Type 1 and 3 Live (Oral) IP	14.01.2025	Nil
4.	M/s Serum Institute of India Pvt. Ltd., S.No.105-110, Manjari BK., Pune-412307, India.	Novavax Covid -19 Vaccine, Adjuvanted 2024-2025 formula 1(Omicron JN.1 variant)	20.02.2025	Nil
5.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune-411028, India	Rota Vaccine Liquid Cipla Liquid for oral administration	20.02.2025	Nil
6.	M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune-411028, India.	1. Diphtheria and Tetanus Vaccine (Adsorbed) for adults and Adolescents (TD Vaccine, Ready to fill bulk (Domestic) . 2. Diphtheria and Tetanus Vaccine (Adsorbed) for adults and Adolescents (TD Vaccine, Ready to fill bulk (Export) .	20.02.2025	Nil
7.	M/s. Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune-411028, India.	Inactivated Salk Polio Vaccine (Adsorbed)	05.03.2025	Nil

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8.	M/s. Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. Diphtheria and Tetanus Vaccine (adsorbed) for adults and adolescents I.P. (Domestic) 2. Diphtheria and Tetanus Vaccine (adsorbed) for adults and adolescents I.P. (Export) 3. Diphtheria and Tetanus Vaccine (adsorbed) for adults and adolescents I.P. SII Td-Vac (Export) 4. Adsorbed Diphtheria and Tetanus Vaccine for Adults and Adolescents B.P. (Export) 5. Adsorbed Diphtheria and Tetanus Vaccine for Adults and Adolescents B.P. SII Td-Vac (Export) 6. Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents (Export/WHO/UNICEF/PAHO) 7. Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents SII TD-VAC (Export/WHO/UNICEF/PAHO) 8. Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents SII TD-VAC (Export/WHO/UNICEF/PAHO) 9. Tetanus and Diphtheria Toxoid (Td) Adult (Injectable Suspension) (Export/WHO/UNICEF/PAHO)	05.03.2025	Nil
9.	M/s.Dano vaccines & Biologicals Private Limited, 575, Sivaryeddyguda, Ghatkesar Village, Ghatkesar Mandal, Medchal-Malkajgiri District- 50130.	1. Bulk purified tetanus toxoid I.P (Domestic) 2. Bulk purified tetanus toxoid I.P DANO-BPTT (Export)	05.03.2025	Nil
10	M/s. Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. BCG Immunotherapy I.P. [Freeze- Dried] (Domestic) 2. BCG Immunotherapy I.P. [Freeze- Dried] (Export) 3. BCG immunotherapy I.P.	24.03.2025	Nil

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		[Freeze- Dried] SII-ONCO-BCG (Export) 4. BCG immunotherapy B.P. [Freeze- Dried] (Export) 5. BCG immunotherapy B.P. [Freeze- Dried] SII-ONCO-BCG (Export)		
11	M/s MSD Pharmaceuticals Pvt. Ltd., at C/o M/s. M/s. Reenav Logistic Pvt. Ltd., H.No. 1124/E-1, Ground Floor, Rajlaxmi Hitech Park, NH3, Sonale Village, Bhiwandi-421302, Dist. Thane, Maharashtra	1. Human Papillomavirus 9-valent vaccine, Recombinant [Serotype: Type 6L1,11 L1, 16 L1, 18L1, 31L1, 33L1, 45L1, 52L1 & 58L1] 2. Human Papillomavirus Quadrivalent (Type 6, 11, 16 & 18) vaccine Recombinant 3. Pneumococcal Polysaccharide Vaccine I.P. 4. Rotavirus Vaccine (Live Attenuated, Oral) I.P. 5. Varicella Vaccine, Live I.P.	03.04.2025	Nil
12	M/s. Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (liquid) (Domestic). 2. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (liquid) (Export). 3. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (liquid) ROTASIIL-LIQUID (Export) 4. Rotavirus Vaccine (Live Attenuated, Oral) (liquid) (Export/WHO/UNICEF/PAHO) 5. Rotavirus Vaccine (Live Attenuated, Oral) (liquid) (Export/WHO/UNICEF/PAHO) 6. Rotavirus Vaccine (Live Attenuated, Oral) (liquid) ROTASIIL-Liquid (Export/WHO/UNICEF/PAHO) 7. ROTA VACCINE LIQUID CIPLA Liquid for Oral administration (Export)	03.04.2025	Nil
13	M/s. Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. Purified HPV Serotype 16 VLP Antigen (Domestic) 2. Purified HPV Serotype 16 VLP Antigen (Export)	03.04.2025	Nil

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14	M/s. Serawin Biologicals LLP situated at Sy. No. 84,89,90 and 91, Mutpoor Village, Kondurg Mandal, Ranga reddy District -509 207, Telangana State, India.	1. Diphtheria Antitoxin Plasma (Equine) 2. Rabies Antiserum Plasma (Equine) 3. Scorpion Venom Antiserum Plasma (Equine) 4. Snake Venom Antiserum Plasma (Equine) 5. Tetanus Antitoxin Plasma (Equine)	07.04.2025	Nil
15	M/s Biological E. Limited, Plot No. 1, Biotech Park, Phase II, Kothur Village, Shameerpet, Medchal-Malkajgiri District-500078, Telangana, India.	1. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. (Reduced Thiomersal) (Ready to fill bulk) (for Domestic and Export Purpose). 2. Diphtheria and Tetanus Vaccine (Adsorbed Reduced Antigen(s) content) (Reduced Thiomersal) (Ready to fill bulk) (for Export Purpose). 3. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. (Reduced Thiomersal) (For Domestic Purpose) 4. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. (Reduced Thiomersal) (For Export Purpose) 5. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content) (Reduced Thiomersal) (For Export Purpose) 6. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content) (Reduced Thiomersal) BE Td (For Export Purpose)	08.04.2025	Nil
16	M/s MSD Pharmaceuticals Pvt. Ltd., at C/o M/s. M/s S K Logistic, Gala No. 3A, 4A, 5 to 10, 11A & 12A, b-4, Citylink Warehousing	1. Human Papillomavirus 9-valent Vaccine, Recombinant [Serotypes: Type 6 L1, 11 L1, 16L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 & 58 L1] 2. Human Papillomavirus	21.04.2025	Nil

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	Complex, S. No. 120-121, Mumbai Nashik Highway, Village- Vadapa Opp. Police Station, Bhiwandi-421302 District: Thane.	Quadrivalent (Type 6, 11, 16 & 18) Vaccine Recombinant 3. Pneumococcal Polysaccharide Vaccine I.P. 4. Rotavirus Vaccine (Live Attenuated, Oral) I.P. 5. Varicella Vaccine Live I.P.		
17	M/s GCBC Vaccines Private Limited, Survey No. 274, Athvelli Village, Medchal Mandal, Medchal - Malkajgiri District – 501401, Telangana, India	1. Cholera Vaccine (Inactivated, Oral) I.P. (Domestic) 2. Cholera Vaccine (Inactivated, Oral) B.P. (Export) 3. Inactivated Bivalent (O1 & O139) Oral Cholera Final Bulk Vaccine [Ready to Fill Bulk] (Domestic) 4. Inactivated Bivalent (O1 & O139) Oral Cholera Final Bulk Vaccine [Ready to Fill Bulk] (Export) 5. Inactivated Bivalent (O1 & O139) Oral Cholera Vaccine Bulk I.P. (Domestic) 6. Inactivated Bivalent (O1 & O139) Oral Cholera Vaccine Bulk B.P. (Export) 7. Tetanus Bulk Purified Toxoid I.P. (Domestic) 8. Tetanus Bulk Purified Toxoid B.P. (Export) 9. Diphtheria Bulk Purified Toxoid I.P. (Domestic) 10. Diphtheria Bulk Purified Toxoid B.P. (Export)	27.05.2025	Nil
18	M/s Pfizer Limited, The Capital – A Wing, 1802, 18 th Floor, Plot No. C-70, G-Block, Bandra-Kurla Complex, Bandra (East), Mumbai-400051 (India)	1. Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed) I.P., 20-Valent (Prevenar 20)	28-05-2025	Nil
19	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India	1. Serogroup A, C, Y, W, X meningococcal polysaccharide conjugate vaccine (Export)	30.05.2025	Nil

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	,411028			
20	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra,India ,412307	1. Purified HPV Serotype 6 VLP Antigen (Domestic) 2. Purified HPV Serotype 6 VLP Antigen (Export)	30.05.2025	Nil
21	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra,India ,412307	1. Purified HPV Serotype 11 VLP Antigen (Domestic) 2. Purified HPV Serotype 11 VLP Antigen (Export)	30.05.2025	Nil
22	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra,India ,412307	1. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Liquid), 4 ml - 2 dose (Glass Vial) (Domestic) 2. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Liquid), 4 ml - 2 dose (Glass Vial) (Export) 3. Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Liquid), 4 ml - 2 dose (Glass Vial) [ROTASIIL-Liquid], (Export) 4. Rotavirus Vaccine, Live Attenuated (Oral) (Liquid), 4 ml - 2 dose (Glass Vial) (Export) 5. Rotavirus Vaccine, Live Attenuated (Oral) (Liquid), 4 ml - 2 dose (Glass Vial), ROTASIIL-Liquid (Export)	30.05.2025	Nil
23	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra,India ,412307	1. covid-19 vaccine, (recombinant), Multidose Vial 2.5 ml- 5 Dose (Export)	30.05.2025	Nil
24	M/s Serum Institute of India Pvt. Ltd., S No 105 - 110, Manjari Bk, Pune, Maharashtra,India ,412307	1. Purified HPV Serotype 18 VLP Antigen (Domestic) 2. Purified HPV Serotype 18 VLP Antigen (Export)	25.06.2025	Nil
25	M/s Biological.E Limited (Sez), SY NO 549, 550, 552 TO 556, KOLTHUR	1. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and	25.06.2025	Nil

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	VILLAGE, SHAMEERPET, Medchal, Telangana, India-500101	Haemophilus influenzae type b conjugate vaccine (Adsorbed) I.P. (DTwP-rHepB-Hib) (For Domestic) 2. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed), (DTwP-rHepB-Hib) (For Export) 3. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (Adsorbed) (DTwP- rHepB-Hib) ComBE Five (Liquid) - (For Export)		
26	M/s Biological.E Limited (Sez), SY NO 549, 550, 552 TO 556, KOLTHUR VILLAGE, SHAMEERPET, Medchal, Telangana, India ,500101	1. Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) - Ready to Fill Bulk, (For Export) 2. Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) I.P. (Ready to Fill Bulk) (For Domestic)	25.06.2025	Nil
27	M/s Panacea Biotech Ltd., Malpur, Baddi, Solan, Himachal Pradesh, India-173205	1. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents IP	25-06-2025	Nil
28	M/s Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. SARS-CoV-2rS JN.1 Variant Drug Substance (Export)	17.07.2025	Nil
29	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Maharashtra, India, 411028	1. Influenza Vaccine (Human, Live Attenuated) I.P., Seasonal, Trivalent (Liquid) (Domestic). 2. Influenza Vaccine (Human, Live Attenuated) I.P., Seasonal, Trivalent (Liquid) (Export). 3. Influenza Vaccine (Human,	17.07.2025	Nil

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		Live Attenuated) I.P., Seasonal, Trivalent (Liquid) NASOVAC S3 (Export). 4. Influenza Vaccine (Human, Live Attenuated) Seasonal, Trivalent (Liquid) (Export).		
30	M/s Zydus Lifescience Limited, Plot No. 23, 25/P, 37, 40/P 42 to 47, 49 & 50 Sarkhej-Bavla National Highway No. 8A, Opp. Ramdev Masala Village: Changodar, Taluka Sanand, Dist. Ahmedabad -382 213, State Gujarat.	1. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) Vial. WHO recommended strain for year 2025 2026 Northern Hemisphere for Influenza season (Domestic). 2. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) PFS. (Vaccine Combipack). WHO recommended strain for year 2025 2026 Northern Hemisphere for Influenza season (Domestic)	01.08.2025	Nil
31	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Maharashtra, India, 411028	1. Purified Rabies Antigen, Ravac Vaccine (Export)	11.08.2025	Nil
32	M/s Biological E. Limited, (Vaccine) Plot No. 1, Biotech Park, Phase II, Kothur Village, Shameerpet, Medchal, Telangana, India ,500101	1. Tetanus Vaccine (Adsorbed) I.P (Domestic) 2. Tetanus Vaccine (Adsorbed) I.P (Export). 3. Adsorbed Tetanus Vaccine B.P. (Export). 4. Adsorbed Tetanus Vaccine B.P. BETT (Export).	11.08.2025	Nil
33	M/s Serum Institute of India Pvt. Ltd., S.No. 105-110, Manjari BK., Pune-412307, India.	1. COVID-19 Vaccine, Adjuvanted, NUVAXOVID (2025-2026 Formula) NUVAXOVID (Export).	11.08.2025	Nil
34	M/s Bharat Biotech International Limited, SY NO 230, 231 & 235, Genome Valley, Turkapally VILLAGE, Shamirpet Mandal, Medchal- Malkajgiri District, Telangana, India, 500078	1. Bivalent Poliomyelitis Vaccine Type 1 and 3, Live (Oral) IP. (Domestic)	29.09.2025	Nil

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35	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India-411028	1. Purified Tetanus Toxoid (Domestic). 2. Purified Tetanus Toxoid (Export)	29.09.2025	Nil
36	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India, 411028	1. Purified Diphtheria Toxoid (Domestic). 2. Purified Diphtheria Toxoid (Export)	29.09.2025	Nil
37	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India, 411028	1. Rubella Vaccine (Live) I.P. (Domestic) 2. Rubella Vaccine (Live) I.P. (Brand Name: R-VAC® PFS) (Export) 3. Rubella Vaccine, Live B.P. (Export) . 4. Rubella Vaccine, Live B.P. (Brand Name: R-VAC® PFS) (Export) 5. Rubella Vaccine, Live Attenuated (Freeze Dried) (Export) 6. Rubella Vaccine, Live, Attenuated (Freeze-Dried) (Brand Name: R-VAC® PFS) (Export) 7. Rubella Vaccine (Live) I.P. (Export)	03.11.2025	Nil
38	M/s Bharat Biotech International Limited, Sy NOo230, 231 & 235, GENOME VALLEY, TURKAPALLY VILLAGE, Shamirpet Mandal, Medchal, Telangana, India-500101	Rotavirus Vaccine (Live Attenuated, Oral) I.P. (Domestic)	17.11.2025	Nil
39	M/s Zydus Lifesciences Limited, Plot Survey No 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla National Highway No 8A, Opposite Ramdev Masala, Village - Changodar, Taluka - Sanand, District - Ahmedabad - 382213, State - Gujarat, India,	3. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Domestic). 4. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Vaccine Combipack) (Domestic). 5. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried). (Brand Name ZyVac® MMR) (Export) 6. Measles, Mumps and	15.12.2025	Nil

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		Rubella Vaccine (Live) I.P. (Freeze Dried). (Vaccine Combipack) (Brand Name ZyVac® MMR) (Export). 7. Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried). (Export) 8. Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried). (Vaccine Combipack). (Brand Name ZyVac® MMR) (Export)		
40	M/s Serum Institute of INDIA Pvt. Ltd. S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114, 168-170 (M), Hadapsar, Pune 411 028 PUNE, Pune, Maharashtra, India ,411028	Amendment in the address on Drug Manufacturing Licence No. in MLF28D2024MH000003 (Form-28D) of M/s Serum Institute of India Pvt. Ltd of the manufacturing premises	15.12.2025	Nil
41	M/s Serum Institute of INDIA Pvt. Ltd. S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114, 168-170 (M), Hadapsar, Pune 411 028 PUNE, Pune, Maharashtra, India ,411028	Amendment in the address on Drug Manufacturing Licence No. in MLF28D2024MH000003 (Form-28D) of M/s Serum Institute of India Pvt. Ltd of the manufacturing premises	15.12.2025	Nil