

Annexure-IV(a):
Details of applications of manufacturing license of vaccines in Form 28D/28DA
and its regulatory status (Approved/Withdrawn) -Jan 2025 to March 2025

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)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

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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. [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)	24.03.2025	Nil
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