

Annexure-IV(a):

Details of applications of manufacturing license of vaccines in Form 28D/28DA and its regulatory status (Approved/Withdrawn) -JAN. 2026 to March 2026

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)
1.	M/s Serum Institute of India Pvt. Ltd., 212/2, HADAPSAR, PUNE, Pune, Maharashtra, India ,411028	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) (Export)	09-01-2026	Nil
2.	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, Ahmedabad, Gujarat, India ,382213	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)	15-01-2026	Nil
3.	M/s Biological E Limited (Vaccine), PLOT NO1, BIOTECH PARK, PHASE II, KOLTHUR VILLAGE, SHAMEERPET, Medchal, Telangana, India ,500101	1. SARS-CoV-2 (Covid-19) Vaccine (Domestic) 2. SARS-CoV-2 (Covid-19) Vaccine (Export) 3. SARS-CoV-2 (Covid-19) Vaccine (Brand Name: CORBEVAX) (Export)	15-01-2026	Nil
4.	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, Ahmedabad, Gujarat, India ,382213	1. Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV-PM] (Domestic) 2. Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV-PM] - Vaccine Combipack (Domestic) 3. Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV-PM] - Vaccine Combipack (Domestic) 4. Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV-PM] - Vaccine Combipack - VaxiRab N (Domestic) 5. Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV-PM] - Vaccine Combipack - VaxiRab N (Domestic)	09.02.2026	Nil

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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 National Highway No 8A, Opposite Ramdev Masala, Village- Changodar, Taluka- Sanand, Ahmedabad, Gujarat, India ,382213	1. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) PFS. (Vaccine Combipack). WHO recommended strain for year 2026 Southern Hemisphere Influenza for Influenza season (Domestic) 2. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) Vial. WHO recommended strain for year 2026 Southern Hemisphere Influenza for Influenza season (Domestic). 3. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) PFS. (Vaccine Combipack). [VaxiFlu-TM]. WHO recommended strain for year 2026 Southern Hemisphere Influenza for Influenza season (Brand Name: VaxiFlu-TM) (Export) 4. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) - 0.5 ml (Single dose) Vial. [VaxiFlu-TM]. WHO recommended strain for year 2026 Southern Hemisphere Influenza for Influenza season (Brand Name: VaxiFlu-TM) (Export)	09.02.2026	Nil
5.	M/s Panacea Biotech Ltd. Malpur, Baddi, Solan, Himachal; Pradesh, India, 173205	Diphtheria, Tetanus, pertussis (whole cell), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) IP (Brand Name: Zyvax Six vaccine) (Domestic) .	24.03.2026	Nil
6.	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	Yellow Fever Vaccine, Live Attenuated (Freeze-Dried) (Export)	24.03.2026	Nil
7.	M/s Human Biologicals Institute (A Division of Indian Immunologicals Limited) Sy No 281-284 & 321, Biotech Park Phase III, Karkapatla Village, Markook Mandal, Siddipet, Telangana, India ,502281	1. Diphtheria and Tetanus vaccine (Adsorbed) for Adults & Adolescents I.P. (Domestic). 2. Diphtheria and Tetanus vaccine (Adsorbed) for Adults & Adolescents I.P.(Export) 3. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content) B.P. (Export)	24.03.2026	Nil