

Annexure-IV(a):
Details of applications of manufacturing license of vaccines in Form 28D/28DA
and its regulatory status (Approved/Withdrawn) -April. 2026 to June 2026

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)
1.	M/s Bharat Biotech International Limited, Sy No 230, 231 & 235, Genome Valley, Turkapally Village, Shamirpet Mandal, Medchal-Malkajgiri, Telangana, India ,500078	1. Rotavirus Vaccine (Live, Oral) B.P. (Brand Name: ROTAVAC 5D®, ROTAVAC5™ & ROTAVAC 5Drops®) (Export)	16.04.2026	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, Ahmedabad, Gujarat, India ,382213	1. Formulated bulk of Typhoid Polysaccharide Vaccine I.P. (Ready to fill) (Domestic) 2. Formulated bulk of Typhoid Polysaccharide Vaccine I.P. (Ready to fill) (Export) 3. Formulated bulk of Typhoid Polysaccharide Vaccine B.P. (Ready to fill) (Export)	12.05.2026	Nil
3.	M/s Bharat Biotech International Limited, Sy No 230, 231 & 235, Genome Valley, Turkapally Village, Shamirpet Mandal, Medchal-Malkajgiri, Telangana, India ,500078	1. Cholera Vaccine (Inactivated, Oral) Bulk drug substance (Export) 2. Cholera Vaccine (Inactivated, Oral) Bulk drug substance (Domestic)	25.05.2026	Nil
4.	M/s Human Biologicals Institute (A Division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Serilingampally, Ranga Reddy, Telangana, India ,500032	1. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Haemophilus Influenza Type b Conjugate Vaccine (Adsorbed) - Ready to fill Bulk (RTFB) (Domestic) 2. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Haemophilus Influenza Type b Conjugate Vaccine (Adsorbed) - Ready to fill Bulk (RTFB) (Export) 3. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Haemophilus Influenza Type b Conjugate Vaccine (Adsorbed) - Ready to fill Bulk (RTFB) (Export)	25.05.2026	Nil
5.	M/s Human Biologicals Institute (A Division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Serilingampally, Ranga Reddy, Telangana, India ,500032	1. Bulk Purified Diphtheria Toxoid I.P. (Domestic) 2. Bulk Purified Diphtheria Toxoid I.P. (Export) 3. Bulk Purified Diphtheria Toxoid B.P. (Export)	25.05.2026	Nil

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6.	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. 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)	09.06.2026	Nil
7.	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. Measles Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) - Single dose Vial. (Domestic) 2. Measles Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) -Single dose vial. (Vaccine Combipack) (Domestic) 3. Measles Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried)-Single dose vial (Vaccine Combipack) (Brand Name: ZyVac MMR) (Export) 4. Measles Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) -Single dose vial (Vaccine Combipack) (Domestic) 5. Measles Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried)- Single dose vial (Vaccine Combipack) (Domestic) 6. Measles Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried) - Single dose vial (Export) 7. Measles Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried) - Single dose vial (Vaccine Combipack) (Export) 8. Measles Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried)-Single dose vial (Vaccine Combipack) (Brand Name: ZyVac MMR) (Export)	09.06.2026	Nil
8.	M/s Bharat Biotech International Limited, Sy No 230, 231 & 235, Genome Valley, Turkapally Village, Shamirpet Mandal, Medchal-Malkajgiri, Telangana, India ,500078	1. Bivalent Poliomyelitis Vaccine Type 1 and 3, Live (Oral) I.P. (Domestic) 2. Bivalent Poliomyelitis Vaccine Type 1 and 3, Live (Oral) (Brand Name: BIOPOLIO® B1/3) (Export)	10.06.2026	Nil