

Annexure-IV(a):
Details of applications of manufacturing license of vaccines in Form 28D/28DA
and its regulatory status (Approved/Withdrawn) -2024

S.No.	Firm Name	Name of the Product	Date of Approval Issued	Withdrawn date (if applicable)
1	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	1. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus Influenza Type b Conjugate vaccine (Adsorbed) BULK (Domestic) 2. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus Influenza Type b Conjugate vaccine (Adsorbed) BULK (Export)	28-02-2024	Nil
2	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	1. Pneumococcal Polysaccharide Conjugate (Adsorbed) (10 Valent) Bulk Vaccine (Ready to fill bulk) (Domestic) 2. Pneumococcal Polysaccharide Conjugate (Adsorbed) (10 Valent) Bulk Vaccine (Ready to fill bulk) (Domestic) (Export)	28-02-2024	Nil
3	M/s ZydusLifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -Bavla N. H. No. 8A, Village: Moraiya, Tal.Sanand, Dist.Ahmedabad - 382210, Gujarat	1. Inactivated Influenza Vaccine (Whole Virion) I.P. (Pandemic Influenza (H1 N1) 2009 Monovalent Vaccine (Embryonated hen egg derived) 0.5 ml single dose 2. Inactivated Influenza Vaccine (Whole Virion) I.P. (Pandemic Influenza (H1 N1) 2009 Monovalent Vaccine (Embryonated hen egg derived) 5.0 ml multi dose 3. Typhoid Polysaccharide Vaccine I.P. 2.5ml in vial multi dose (05 dose) 4. Typhoid Polysaccharide Vaccine I.P. 5.0 ml in vial multi dose (10 dose) 5. Typhoid Polysaccharide Vaccine I.P. 0.5ml in PFS single dose 6. Typhoid Polysaccharide Vaccine B.P. 0.5ml in vial single dose (For export) 7. Typhoid Polysaccharide Vaccine B.P. 2.5ml in vial single dose (For	08-03-2024	Nil

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	<p>export)</p> <p>8. Typhoid Polysaccharide Vaccine I.P. 0.5ml in vial single dose for export</p> <p>9. Typhoid Polysaccharide Vaccine B.P 0.5ml in PFS single dose for export</p> <p>10. Typhoid Polysaccharide Vaccine B.P 5.0ml in vial Multi dose (10 dose)</p> <p>11. Typhoid Polysaccharide Vaccine I.P 0.5ml in vial single dose</p> <p>12. Typhoid Polysaccharide Vaccine I.P VACTYPH For export</p> <p>12. Typhoid Polysaccharide Vaccine I.P. VACTYPH For export</p> <p>13. Typhoid Polysaccharide Vaccine B.P VACTYPH For export</p> <p>14. Typhoid Polysaccharide Vaccine B.P VACTYPH For export</p> <p>15. Typhoid Polysaccharide Vaccine B.P VACTYPH 2.5ml in vial mulit dose (05 dose) for export</p> <p>16. Typhoid Polysaccharide Vaccine B.P VACTYPH 5.0ml in vial multi dose (10 dose) for export</p> <p>17. Typhoid Vi Conjugate Vaccine I.P.</p> <p>18. Typhoid Vi Conjugate Vaccine I.P.</p> <p>19. Typhoid Vi Conjugate Vaccine I.P. Single dose (0.5ml) Vial</p> <p>20. Typhoid Vi Conjugate Vaccine I.P. Single dose 0.5ml vial</p> <p>21. Typhoid Vi Conjugate Vaccine I.P. Single dose 0.5ml vial</p> <p>22. Typhoid Vi Conjugate Vaccine I.P. Multi dose 2.5ml vial</p> <p>23. Typhoid Vi Conjugate Vaccine I.P. Multi dose 2.5ml vial Zy VaC TCV</p> <p>24. Typhoid Vi Conjugate Vaccine Multi dose 2.5ml vial Zy VaC TCV</p> <p>25. Typhoid Vi Conjugate Vaccine I.P. Multi dose 2.5ml vial</p> <p>26. Typhoid Vi Conjugate Vaccine I.P. Zy VaC TCV Single dose 0.5ml vial</p> <p>27. Typhoid Vi Conjugate Vaccine I.P. Zy VaC TCV Single dose 0.5ml vial</p>		
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		<p>PFS</p> <p>28. Typhoid Vi Conjugate Vaccine I.P. Zy VaC TCV Multi dose 2.5ml vial</p> <p>29. Typhoid Vi Conjugate Vaccine I.P. Single dose 0.5ml PFS For export</p> <p>30. Typhoid Vi Conjugate Vaccine I.P. Zy VaC TCV Single dose 0.5ml vial PFS For export</p> <p>31. Formulated Bulk of Typhoid Polysaccharide Vaccine I.P. (Ready to fill)</p> <p>32. Formulated Bulk of Typhoid Polysaccharide Vaccine I.P. (Ready to fill) For export</p> <p>33. Formulated Bulk of Typhoid Polysaccharide Vaccine B.P. (Ready to fill) For export</p> <p>34. Tetanus Vaccine (Adsorbed) I.P.</p> <p>35. Bulk Purified Tetanus Toxoid I.P.</p> <p>36. Diphtheria, Tetanus and Pertussis (Whole Cell) Vaccine (Adsorbed I.P.</p> <p>37. Diphtheria, Tetanus and Pertussis (Whole Cell) Vaccine (Adsorbed) for adult and adolescents I.P.</p> <p>38. Diphtheria, Tetanus and Vaccine (Adsorbed) for adult and adolescents I.P.</p> <p>39. Diphtheria, Tetanus and Vaccine (Adsorbed) for adult and adolescents B.P. For Export</p> <p>40. Diphtheria, Tetanus and Vaccine (Adsorbed) for adult and adolescents B.P. Zy VaC Td For Export</p> <p>41. Clarified Measles single Harvest (Bulk) DS</p> <p>42. Measles Vaccine (Live) I.P. (Freeze Dried) Single dose Vial</p> <p>43. Measles Vaccine (Live) I.P. (Freeze Dried) Multi dose vial 10 dose</p> <p>44. Measles Vaccine (Live) I.P. (Freeze Dried) Single dose Vial</p>		
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		<p>45. Measles Vaccine (Live) I.P. (Freeze Dried) Single dose Vial</p> <p>46. Measles and Rubella Vaccine (Live) I.P.(Freeze Dried) Single dose vial</p> <p>47. Measles and Rubella Vaccine (Live) I.P.(Freeze Dried) Multi dose vial 10 dose</p> <p>48. Measles and Rubella Vaccine (Live) I.P.(Freeze Dried) Mulit dose vial 05 dose</p> <p>49. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>50. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Multi dose vial 10 dose</p> <p>51. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>52. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Multi dose vial</p> <p>53. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>54. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) single dose vial</p> <p>55. Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried) Single dose vial</p> <p>56. Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried) Multi dose vial 10 dose</p> <p>57. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Zy Vac MMR for export</p> <p>58. Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Zy Vac MMR for export</p> <p>59. Measles, Mumps and Rubella Vaccine (Live) B.P. (Freeze Dried) Zy Vac MMR for export</p> <p>60. Measles, Mumps and Rubella</p>		
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		<p>Vaccine (Live) B.P. (Freeze Dried) Zy Vac MMR for export</p> <p>61. Clarified & concentrated Mumps (Bulk) DS</p> <p>62. Clarified and Concentrated Rubella Single Harvest (Bulk) DS</p> <p>63. Varicella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>64. Varicella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>65. Varicella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>66. Varicella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>67. Varicella Vaccine (Live) I.P. (Freeze Dried) Single dose vial</p> <p>68. Varicella Vaccine (Live) B.P. (Freeze Dried) Single dose vial For export</p> <p>69. Varicella Vaccine (Live) I.P. (Freeze Dried) Single dose vial For export</p> <p>70. Novel Corona virus-2019-nCoV vaccine (Recombinant)</p> <p>71. Novel Corona virus-2019-nCoV vaccine (Recombinant) Ten dose 2ml glass vial</p> <p>72. Novel Corona virus-2019-nCoV vaccine (Recombinant) DS</p> <p>73. Novel Corona virus-2019-nCoV vaccine (Recombinant) ZyCoV-D Ten dose 2ml glass vial</p> <p>74. Novel Corona virus-2019-nCoV vaccine (Recombinant) 2ml in USP type 1 glass vials</p> <p>75. Novel Corona virus-2019-nCoV vaccine (Recombinant) 2ml in USP type 1 glass vials</p> <p>76. Novel Corona virus-2019-nCoV vaccine (Recombinant) 2ml in USP type 1 glass vials</p> <p>77. Novel Corona virus-2019-nCoV vaccine (Recombinant) 2ml in USP type 1 glass vials for export</p> <p>78. Novel Corona virus-2019-nCoV</p>		
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		vaccine (Recombinant) ZyCoV-D 2ml in USP type 1 glass vials for export		
4	M/s ZydusLifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -Bavla N. H. No. 8A, Village: Moraiya, Tal.Sanand, Dist.Ahmedabad - 382210, Gujarat	1. Formulated bulk of Typhoid Polysaccharide Vaccine I.P.(Ready to fill) 2. Formulated bulk of Typhoid Polysaccharide Vaccine I.P.(Ready to fill) For export 3. Formulated bulk of Typhoid Polysaccharide Vaccine B.P.(Ready to fill) For export	22-03-2024	Nil
5	M/s Dr. Reddy's Laboratoties Ltd	Name Change Director-Mr. Sanjiv Soshil Mehta	23-04-2024	Nil
6	M/s Dr. Reddy's Laboratoties Ltd	Name change Dr. Claudio Albrecht Director	23-04-2024	Nil
7	M/s Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -Bavla N. H. No. 8A, Village: Moraiya, Tal.Sanand, Dist.Ahmedabad - 382210, Gujarat	1. Clarified Measles Single Harvest (Bulk) B.P. - DS For export 2. Clarified & Concentrated Mumps (Bulk) B.P. - DS 3. Clarified and Concentrated Rubella Single Harvest (Bulk) B.P. - DS	09-04-2024	Nil
8	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	R21 Malaria Vaccine (Recombinant, Adjuvanted)	12-04-2024	Nil

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9	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	Poliomyelitis Vaccine Oral Bivalent type 1 and 3	12-04-2024	Nil
10	M/s ZyduSLifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -Bavla N. H. No. 8A, Village: Moraiya, Tal.Sanand, Dist.Ahmedabad - 382210, Gujarat	1. Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) 0.5ml (Single dose) PFS 2. Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) 0.5ml (Single dose) PFS VaxiFlu-4 for export 3. Inactivated Influenza Vaccine (Split Virion) B.P. (Tetravalent) 0.5ml (Single dose) PFS, WHO recommended strain 2024-2025 (Northern Hemisphere) for export 4. Inactivated Influenza Vaccine (Split Virion) B.P. (Tetravalent) 0.5ml (Single dose) PFS VaxiFlu-4 For export	06-05-2024	Nil
11	M/S Pfizer Ltd C/o keyur Phamacem India Pvt Ltd	1. Pneumococcal Polysaccharide Conjuage Vaccine (adsorbed) I.P. 13-Valent single dose [Prevenar 13 adult] 2. Pneumococcal Polysaccharide Conjuage Vaccine (adsorbed) I.P. 13-Valent Mult dose vial (Prevenar 13) 3. Pneumococcal Polysaccharide Conjuage Vaccine (adsorbed) I.P. 13-Valent Single dose Pre-filled Syringe	14-05-2024	Nil
12	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	Rabies Vaccine (Freeze Dried)Combipack	14-05-2024	Nil
13	M/s Panacea Biotech Ltd., Village Malpur, Baddi, Distt Solan (H.P.)	Diphtheria, Tetanus, pertussis (Whole Cell) and Haemophilus Influenza type b Conjugate Vaccine (Adsorbed) I.P. (EasyFour-TT and Easysix)	14.05.2024	Nil

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14	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	1. Measles and Rubella Vaccine, Live I.P. (Domestic) 2. Measles and Rubella Vaccine, Live I.P. (Export) 3. Measles and Rubella Vaccine, Live I.P. MR-VAC (Export) 4. Measles and Rubella Vaccine, Live Attenuated (Freeze Dried) (Export/WHO/Unicef)	29-07-2024	Nil
15	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	1. TRIVAID (Live attenuated Measles, Mumps and Rubella Vaccine) Measles. Mumps and Rubella (MMR) Vaccine (Export) 2. TRIVAID (Live attenuated Measles, Mumps and Rubella Vaccine) Measles. Mumps and Rubella (MMR) Vaccine (Export)	29-07-2024	Nil
16	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	1. Measles Vaccine Live I.P. (Domestic) 2. Measles Vaccine Live I.P. (Export) 3. Measles Vaccine Live I.P. M-VAC (Export) 4. Measles Vaccine Live B.P. (Export)	29-07-2024	Nil
17	M/s ZydusLifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -Bavla N. H. No. 8A, Village: Moraiya, Tal.Sanand, Dist.Ahmedabad - 382210, Gujarat	Rabies Vaccine human I.P. Purified Chick embryo Cell culture [PCECV]	05-07-2024	Nil
18	M/s. Biological E. Limited, Plot no. 1, Biotech Park, Phase II, Kolthur village, Shameerpet Mandal, Malkajgiri District-500 078 (Telangana).	1. Pneumococcal Polysaccharide Conjuage Vaccine (Adsorbed) I.P. (14 Valent) (For export and domestic) 2. Pneumococcal Polysaccharide Conjuage Vaccine (Adsorbed) I.P. (14 Valent) (For export)	10-07-2024	Nil
19	M/s Panacea Biotech Ltd., Village Malpur, Baddi, Distt Solan (H.P.)	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) Haemophilus Influenza Type b Conjugate Vaccine (Adsorbed) IP	18.07.2024	Nil

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		(DTwP-HeP B-Hib)-Easy Five TT Vaccine Pentavalent vaccine		
20	M/s. Biological E. Limited, Plot no. 1, Biotech Park, Phase II, Kolthur village, Shameerpet Mandal, Malkajgiri District-500 078 (Telangana).	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Influenza Type b Conjugate Vaccine (Adsorbed)	10.07.2024	Nil
21	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	1. COVID-19 Vaccine, Adjuvanted 2023-24 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine, Omicron XBB.1.5 Variant] {Domestic} 2. COVID-19 Vaccine, Adjuvanted 2023-24 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine, Omicron XBB.1.5 Variant] {Export} 3. COVID-19 Vaccine, Adjuvanted 2023-24 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle vaccine, Omicron XBB.1.5 Variant] COVOVAX {Export} 4. COVID-19 Vaccine, (recombinant, adjuvanted) NUVAXOVID XBB.1.5 (Export)	29.07.2024	Nil
22	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	Rabies Vaccine Human	23.08.2024	Nil
23	M/s Bharat Biotech international limited, Sy. No. 230,231 & 235, Genome Valley, Shameerpet Mandal Medchal-Malkajgiri District, Hyderabad, Telangana	Cholera Vaccine (Inactivated, Oral) I.P	16.08.2024	Nil
24	M/s. Serum Institute of India Pvt. Ltd., S. No. 105-110, Manjari Budruk, Pune – 412301	Covid Vaccine (recombinant adjuvanted) Omicron JN.1 Variant	30.08.2024	Nil