Annexure-II of QMS-INS-002

"Format for Annual Central Inspection Plan for Vaccine Manufacturing Facilities"

Central Drugs Standard Control Organization

Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi -110002

S. No.	Name and address of the manufacturing site	Vaccines manufactured (category wise list)	Date of last inspection with no of days & team	Purpose of last inspection (grant /renewal /post-approval changes, AEFI, follow-up, routine)	Major deficiencies detected	Compliance met till date, if any	AEFI reported/ changes/ Product complaints, failure, if any	Proposed time of Inspection
A	**West Zone**							
1	M/s. Serum Institute of India Ltd., 212/2, Hadapsar, Pune – 411028	TT, DT, DPT, Rabies, Hib, Meningococcal A Conjugate Vaccine, Influenza Vaccine, BCG, Measles, Rubella, MMR, Flu Vaccine for TT, DTP, HiB, DTP HiB Hep.B, Rabies Vaccine, H1N1	13.12.2022 & 14.12.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	Routine Inspection and grant of Additional Product Permission to manufacture Recombinant CRM197 Frozen Bulk for sale or for distribution purposes	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	4th quarter of 2023
2	M/s. Haffkine Bio-Pharmaceutical Corpn. Ltd., Acharya Donde Marg, Parel, Mumbai.	OPV	23.11.2022 & 24.11.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	Revalidation of COPP for OPV	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	4th Quarter of 2023
3	M/s. Serum Institute of India Pvt. Ltd., S. No. 105-110, Manjari Budruk, Pune – 412301	TT, DT, DPT, Rabies, Hib, Meningococcal A Conjugate Vaccine, Influenza Vaccine, BCG, Measles, Rubella, MMR, Flu Vaccine for TT, DTP, HiB, DTP HiB Hep.B, Rabies Vaccine, H1N1	09.11.2022 & 10.11.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	Issuance of WHO-GMP Certification/ COPP for additional product BCG	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st Quarter of 2023
4	M/s. Gennova Biopharmaceuticals Limited, Block 1, Plot No. P-1 & P-2, ITBT Park, Phase II, MIDC, Hinjewadi, Pune, Maharashtra-411057	Lyophilized mRNA Vaccine for Injection (COVID-19).	22.11.2021 & 23.11.2021 Drugs Inspectors of CDSCO, SLA and Subject Expert	Application for license of stock piling mRNA Bulk for Vaccine (COVID-19) and Lyophilized mRNA Vaccine for Injection (COVID-19).	As per report	NA	-	1st Quarter of 2023

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5	M/s. Wockhardt Limited, Formulation mfg site - E-1/1,Wockhardt infrastructure Development Ltd, SEZ, Shendra, Aurangabad.	Sputnik Light & Sputnik V mfg facility	16.12.2021 & 17.12.2021 Drugs Inspectors of CDSCO and SLA	Sputnik Light & Sputnik V mfg facility	Nil	Observations communicated to the firm for compliance and to be verified in the follow up inspection	Nil	1st Quarter of 2023
6	M/s. Wockhardt Limited, Bulk mfg site – H - 14/2A, MIDC, Waluj, Aurangabad	Sputnik Light & Sputnik V mfg facility Viral Vaccine (Drug substances)*	14th and 15th December 2021 Drugs Inspectors of CDSCO, SLA and Subject Expert	Grant of additional product (Bulk of component I (Recombinant adenoviral particles of serotype 26 containing the protein S gene of the SARS-Cov-2 virus) (Sputnik V vaccine)	Nil	Observations communicated to the firm for compliance and to be verified in the follow up inspection	Nil	1st Quarter of 2023
B	**North Zone:**							
1	M/s Biomed Pvt. Ltd, C-96, Site —l. Bulandshahar Road, Ind. Area, Ghaziabad.	1. Oral polio vaccine IP, 2. Vi polysaccharide Typhoid Vaccine (bio Typh TM) IP, 3. Haemophilus Type B Conjugate Vaccine (PedaHib) 4. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W, 135) 5. Meningococcal Polysaccharide Vaccine (Group A&C) Biovalent 6. Vi Conjugate Typhoid Vaccine (Peda Typh)	18.10.2022 Drugs Inspectors of CDSCO and SLA	Compliance verification	As per report	Observations communicated to the firm for compliance.	NA	1" Quarter Routine Inspection 2nd Quarter Follow-up Inspection (if any) 3rd Quarter Routine Inspection 4th Quarter

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		7. Vi Conjugate typhoid Vaccine (Bio TyphTM), 8. Haemophilus Type –B Conjugate Vaccine (PedaHib) IP 9. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W, 135) IP QuadriMeningo 10. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W, 135) Ph Euro Quadri Meningo 11. Meningococcal Polysaccharide Vaccine (Group A & C) Bimeningo 12. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W, 135) Quadri Meningo, Nm Vac-4 ACYW 135, 13. Veterinary Vaccine						Follow-up Inspection (if any)
2	M/s Bharat Immunologicals & Biologicals Corporation Limited (BIBCOL), Village Chola. Dist.	1. Oral Polio Vaccine IP	01.04.2022 Drugs Inspectors of CDSCO and SLA	Compliance verification	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	NA	2nd Quarter Routine Inspection 4th Quarter Follow-up Inspection (if any)
C	**South Zone:**							

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1	M/s. Green Signal Biopharrna Pvt. Ltd., No. 49, Pappankuppam Village, Gummidipoondi, Chennai 601 201	1. BCG Vaccine (Freeze-Dried) IP/BP/EP/USP 2. BCG for Immunotherapy (Freeze dried) BP/EPP/USP	1. 19.09.2022 to 21.09.2022 2. 01.12.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	1. To verify the compliance verification of previous joint inspections held on 22-26th October 2018, 15-18th July 2019, 25-29th July 2019 and 28-29th October 2021 and Refurbishment or up gradation of the factory under post approval changes 2. Verification of the CAPA	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	Nil	2nd quarter
2	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Kozhipannai, Pudumund Post, Udhagamandalam-643007, Tamil Nadu	Rabies Vaccine, Human IP, BP, Purified Rabies bulk antigen	1. 14.03.2022 to 16.03.2022 2. 07.07.2022 & 08.07.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	1. Annual inspection along with revalidation of COPP and follow up inspection of the earlier inspection. 2. Postapproval changes made with respect to removal of LAF Unit from infection and harvest area in addition as a stand by unit to the existing cold room for storage of Rabies viral harvest.	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st quarter follow up inspection for verification of CAPA
D	**Ahmedabad Zone:**							
1	M/s Chiron Behring Vaccines Pvt. Ltd., Plot No. 3502, G.I.D.C. Estate, P.	1. Inactivated Purified Chick Embryo Cell Rabies Vaccine IP/BP	16/11/2022 & 17/11/2022 Drugs Inspectors	For Renewal of WHO-GMP Certificate under WHO-GMP Certification Scheme	As per report	Observations communicated to the firm for compliance and	-	2nd Quarter Routine Inspection

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	B. No. 136, Ankleshwar, Dist :- Bharuch - 393002, Gujarat	(Viral Vaccine) 2. Monkeypox Vaccine (Viral Vaccine) [Manufactured under Test License] 3. Malarial Vaccine (Parasite Vaccine) [Manufactured under Test License] 4. Whole Viron, Inactivated Coronavirus Vaccine, COVAXIN (Viral Vaccine) [Manufactured under Loan Licence of M/s Bharat Biotech International Limited]	of CDSCO, SLA and Subject Expert			to be verified in the follow up inspection		4th Quarter Follow up inspection
2	M/s Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 23, 25/P, 40/P, 42 to 47, Sarkhej - Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Tal. Sanand, Dist.	1. Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) 0.25 mL PFS. 2. Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) 0.5 mL 3. Tetanus Vaccine (Adsorbed) I.P. 4. Bulk Purified Tetanus Toxoid IP 5. Measles Vaccine (Live) I.P. (Freeze Dried) - Single	07/10/2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	Routine Inspection and verification adequacy of data for post approval changes in Bulk Purified Tetanus Toxoid I.P., Purified Vi Polysaccharide S. Typhi Bulk (NP), Typhoid Vi Polysaccharide- TT Conjugate Bulk and modification in Drug Product manufacturing facility (Plant 3B, Bacterial Vaccine Production)	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st Quarter Routine Inspection 3rd Quarter Follow-up inspection

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	Ahmedabad - 382 213, Gujarat	Dose Vial 6. Measles Vaccine (Live) I.P. (Freeze Dried) - Single Dose Vial (Combipack with WFI, Syringe & needle. 7. Measles Vaccine (Live) I.P. (Freeze Dried) - Multi dose Vial (10 dose) 8. Measles & Rubella Vaccine (Live) IP (Freeze dried) Single dose Vial 9. Measles & Rubella Vaccine (Live) IP (Freeze dried) Multi dose Vial (05 dose) 10. Measles & Rubella Vaccine (Live) IP (Freeze dried) Multi dose Vial (10 dose) 11. Measles Mumps Rubella Vaccine (Live) IP (Freeze Dried) Single dose Vial 12. Measles Mumps Rubella Vaccine (Live) IP (Freeze Dried) Single dose Vial (Combi pack with WFI, Syringe and needle.) 13. Measles Mumps Rubella Vaccine (Live) IP (Freeze						

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		Dried) Multi dose Vial (10 dose) 14. Measles Mumps Rubella Vaccine (Live) IP (Freeze Dried) Multi dose Vial (10 dose) (Combipack with WFI, Syringe and needle) 15. Diphtheria, Tetanus & Pertusis (Whole Cell) Vaccine (Adsorbed) I.P. 16. Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) 0.5 mL 17. Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) 0.5 mL (Single Dose) PFS. 18. Inactivated Influenza Vaccine (Split Virion) BP (Tetravalent) 0.5 mL (Single Dose) PFS 19. Varicella Vaccine (Live) IP (Freeze dried) 20. Varicella Vaccine (Live) IP (Freeze dried)(Combi pack with WFI, Syringe and needle) 21. Varicella Vaccine (Live) BP (Freeze dried) 22. Typhoid Polysaccharide						

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		Vaccine IP 2.5 mL in Vial Multidose (05 dose) 23. Typhoid Polysaccharide Vaccine IP 5.0 mL in Vial Multidose (10 dose) 24. Typhoid Polysaccharide Vaccine IP 0.5 mL PFS 25. Typhoid Polysaccharide Vaccine IP 0.5 mL in Vial 26. Typhoid Polysaccharide Vaccine BP 0.5 mL in PFS 27. Typhoid Polysaccharide Vaccine BP 0.5 mL in Vial (Single Dose) 28. Typhoid Polysaccharide Vaccine BP 2.5 mL in Vial Multi dose (05 dose) 29. Typhoid Polysaccharide Vaccine BP 5.0 mL in Vial Multi dose (10 dose) 30. Typhoid Vi Conjugate Vaccine IP Single Dose Vial 31. Typhoid Vi Conjugate Vaccine IP Single Dose Vial (Combipack with disposable syringe and needle) 32. Typhoid Vi Conjugate Vaccine IP Single Dose						

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		PFS 33. Formulated Bulk of Typhoid Polysaccharide Vaccine IP (Ready-to-fill) 34. Formulated Bulk of Typhoid Polysaccharide Vaccine BP (Ready-to-fill) 35. Novel Corona Virus - 2019-nCov Vaccine (Recombinant) Two dose (0.5 mL) Glass Vials 36. Novel Corona Virus-2019-nCov Vaccine (Recombinant) Ten dose (2.0 mL) Glass Vials 37. Novel Corona Virus - 2019-nCov Vaccine drug substance 38. Novel Corona Virus - 2019-nCov Vaccine 2.0 mL (Recombinant) in Pharmajet Tropis device						
3	M/s Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -	Rabies Vaccine Human I.P. / Rabies Vaccine B.P. (Purified Chick Embryo Cell Culture Rabies Vaccine)	27/09/2022 & 28/09/2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	For Renewal of WHO-GMP Certificate under WHO-GMP Certification Scheme	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	2nd Quarter Routine Inspection 4th Quarter Follow up inspection (if any)

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	Bavla N. H. No. 8A, Village: Moraiya, Tal. Sanand, Dist. Ahmedabad - 382 210, Gujarat							
4	M/s Cadila Pharmaceuticals Limited, 1389, Dholka - 382 225, Dist. Ahmedabad, Gujarat	1. Trivalent seasonal influenza virus like particles (VLPs) Vaccine 0.5 ml/Vial 2. Monovalent Influenza A (H1N1 2009) Virus like Particles (VLPs) Vaccine 3. Recombinant Rabies G Protein Vaccine 2 mL Glass Vial	15/11/2022 & 16/11/2022 Drugs Inspectors of CDSCO and SLA	For Addition of section of Vaccine category in existing WHO-GMP Certificate	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	Nil	1st Quarter Routine Inspection 3rd Quarter Follow up inspection (if any)
E	**Hyderabad Zone**							
1	M/s Sanofi Healthcare India Private Limited, Sy. No. 354 Muppireddypally, (V), Toopran (M), Medak Dist, T.S.	Cholera Vaccine (Inactivated, Oral), DTP (Wc), Hepatitis B, (rDNA) & Hib Conjugate Vaccine (Adsorbed)	05.11.2020 to 06.11.2020 Drugs Inspectors of CDSCO, SLA and Subject Expert	For annual routine GMP inspection as per Central Inspection Plan -2020 and for verification of CAPA w.r.t Annual inspection dated 08.11.2019 to 09.11.2019 and 21.02.2018 to 22.02.2018	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st Quarter annual inspection 3rd Quarter follow up inspection (if any) & annual inspection
2	M/s Biological E Ltd., D.no. 7-4-37 Gagan Pahad Rajendra Nagar	Tetanus Vaccine (Adsorbed (Bulk) , Diphtheria Antitoxin 1000 I.U. (Bulk), Diphtheria Antitoxin 20000 I.U. (Bulk)	22.10.2020 to 23.10.2020 Drugs Inspectors	1. For Annual routine GMP inspection as per Central inspection plan 2020 and for verification of CAPA	As per report	Observations communicated to the firm for compliance and to be verified in	-	1st Quarter annual inspection

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	(Mandal), R.R. Dist T.S.	Tetanus Antitoxin (Bulk)	of CDSCO, SLA and Subject Expert	verification against previous inspection 2. For verification of manufacturing and quality control facilities used for manufacturing of final bulk SARS-COV-2 (COVID-19) Antiserum immunoglobulin for Clinical trial.		the follow up inspection		3rd Quarter follow up inspection (if any)
3.	M/s Human Biologicals Institute Survey No. 281 to 284 and 321 Karkapatla (V) Medak Dist 502281 TS	Inactivated Rabies Vaccine	05.12.2022 & 06.12.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	Inspection of manufacturing facility (D.S. in block KH08 & D.P. in KH07) used for manufacture of Japanese Encephalitis Vaccine Inactivated (adsorbed) Human for examination, test and analysis under CT-11 on campaign basis	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st Quarter annual inspection 3rd Quarter follow up inspection (if any)
4	M/s Bharat Biotech International Ltd. Genome Valley Tukeypally, Shameerpet (Mandal) hyderabad 500078 , TS	Hepatitis B Vaccine VI Polysaccharide Typhoid Vaccine, Hib, DTP + Hib+Hep, rabies Vaccine, oral polio vaccines, (Topv), ORAL ROTAVIRUS VACCINE, Covid Vaccine (Covaxin)	28.11.2022 & 29.11.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	For grant of additional product manufacturing license in Form 28D to manufacture "(INCOVACC) Covid-19 Vaccine (ChAd36-SARS-COv-S (recombinant)"Bulk Drug Substance and Covid-19 Vaccine (ChAd36-SARS-COv-S (recombinant) single Dose 0.5 ml in PFS and 1 ml vial (2 Dose)	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st Quarter annual inspection 3rd Quarter follow up inspection (if any)
5	M/s. Human Biologicals Institute	Hepatitis B Vaccine Tetanus Toxoid Vaccine (Absorbed)	26.09.2022& 27.09.2022	For grant of additional Product manufacturing license in Form	As per report	Observations communicated to the firm for	-	1st Quarter annual

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	(A Division of Immunological Limited) Rakshapuram Gachibowli Hyderabad 500019, T.S	DTP Vaccine and Inactivated Rabies Vaccine	Drugs Inspectors of CDSCO, SLA and Subject Expert	28D to manufacture following products: 1. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults & Adolescents I.P (For Domestic & Export) 2. Diphtheria and Tetanus Vaccine (Adsorbed, Reduced Antigen(s) Content) (For export) 3. Measles and Rubella Vaccine (Live) I.P for (For Domestic & Export) and Measles and Rubella Vaccine (Live) for (For Export)		compliance and to be verified in the follow up inspection		inspection 3rd Quarter follow up inspection (if any) Annual inspection
6	M/s Sanofi Healthcare India Pvt. Ltd. Survey No. 274 Athvelli Village Medchal Mandal 501401 Malkajgiri Telangana	Hepatitis B Vaccine, DTP, DTP+ Hepatitis B, DTP+ Hepatitis+Hib TT, Hib DTP+ Hib, Oral Cholera Vaccine, Hepatitis B Vaccine Bulk TT, TT Bulk, DTP+Hep+Hib Bulk	5.1.2022, 6.1.2022 & 7.1.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	For grant of manufacturing license in Form 28D for following additional products: 1. Bordetella Pertussis (Whole cell inactivated) (Bulk) I.P., 2. Diphtheria, Tetanus Pertussis (Whole cell), Hepatitis B (rDNA) Haemophilus Influenza Type b Conjugate and Poliomyelitis (Inactivated) (Adsorbed) Final Bulk Vaccine [Ready to Fill Single Dose] 3. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	2nd quarter Annual inspection 4th quarter follow up inspection (if any) & annual inspection

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				(rDNA), Haemophilus Influenza Type b Conjugate and Poliomyelitis (Inactivated) (Adsorbed) Final Bulk Vaccine [Ready to Fill Multi Dose] 4. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Influenza Type b Conjugate (Adsorbed) Final Bulk Vaccine [Ready to Fill] 5. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA), Haemophilus influenza Type b Conjugate vaccine (Adsorbed) I. P., 6. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA), Haemophilus influenza				
7	M/s. Dano Vaccines & Biological Pvt. Limited, 575, Sivareddyguda, Ghatkesar (M), R.R. Dist.- 501 302, T.S	Dedicated bulk antigen facility of TT Bulk purified Toxoid IP-NLT 2500Lf/mL, Adsorbed Tetanus Vaccine BP, Bulk Purified Toxoid BP- NLT 2500 Lf/mL	15.09.2022 to 16.09.2022 Drugs Inspectors of CDSCO and SLA	For grant of WHO-GMP certificate for Tetanus Toxoid product in vial and ampoule presentations	As per Report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	2nd quarter Annual inspection 4th quarter follow up inspection (if any) & annual inspection

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8	M/s. Biological E. Limited, 18/1 & 3, Azamabad, Hyderabad, T.S.	Tetanus Vaccine (Adsorbed), DTP Vaccine (Adsorbed),DT Vaccine (Adsorbed), Tetanus Antitoxin, Diptheria antitoxin, JE Inactivated Vaccine	03.08.2022 & 04.08.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	To verify the tenets of GMP, manufacturing process and dossier w.r.t addition of an Identical filling (Fill-Finish) suite Filling Line: 04 (ampoule) for Tetanus Vaccine (Adsorbed) IP- 0.5ml Ampoules	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	2nd quarter Annual inspection 4th quarter follow up inspection (if any) & annual inspection
9	M/s. Biological E Limited., Plot No. 1, SP Biotechnology Park, Phase-II, Kolthur Village, Shameerpet Mandal, R.R.Dist, T.S.	DTPw (Whole cell), Diptheria, Pertusis Hepatitis B Vaccine bulk, JE Vaccine, TT, Hepatitis B, DTP + Hep+Hib	18.10.2022 & 19.10.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	To verify the tenets of GMP, manufacturing and quality control facilities used for manufacturing of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent), Drug Substance and Drug Product 0.5 mL and 2.5mL (Serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F) under Form 28D.	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	2nd quarter Annual inspection 4th quarter follow up inspection (if any) & annual inspection
10	M/s. Biological E. Limited, Sy. No: 549, 550, 552 to 556, Kolthur Village, SEZ facility, Shameerpet, Medchal-Malkajgiri (D), Telanagana-500078	MR Vaccine	24.11.2022 to 25.11.2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	For grant of permission to manufacture "Monovalent Polio virus (Type 2) OPV2 Vaccine (Drug Substance and Drug product)" for examination test and analysis under CT-11.	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	2nd quarter Annual inspection 4th quarter follow up inspection (if any) & annual inspection

Central Drugs Standard Control Organization

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FDA Bhavan, ITO, Kotla Road, New Delhi -110002

S. No.	Name and address of the manufacturing site	Vaccines manufactured (category wise list)	Date of last inspection with no of days & team	Purpose of last inspection (grant /renewal /post-approval changes, AEFI, follow-up, routine)	Major deficiencies detected	Compliance met till date, if any	AEFI reported/ changes/ Product complaints, failure, if any	Proposed time of Inspection
F	**Indore Sub Zone:**							
1	M/s Bio Vaccines (India) Pvt. Ltd. 46-A, sanwar Road Industrial Area Indore (M.P. 452015	Tetanus Vaccine (Adsorbed)IP 0.5 ml (Single dose) & 5.0 ml (Multiple dose	15.03.2022 & 16.03.2022 Drugs Inspectors of CDSCO and SLA	For grant of CoPPs as per WHO-GMP certification scheme for the tetanus vaccine (adsorbed) IP 0.5 ml single dose ampoules and 5ml 10 doses vials	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st quarter Annual inspection 2nd quarter follow up inspection (if any)
G	**Baddi Sub Zone:**							
1	M/s Panacea Biotech Ltd. Village Malpur Baddi, Distt Solan (H.P.)	1. Diphtheria, Tetanus, Pertusis (Whole cell), Hepatitis B (rDNA) and Haemophilus Influenza Type b conjugate vaccine (Adsorbed) IP (Easyfive-TT) 2. Diphtheria, Tetanus & Pertusis vaccine (adsorbed) IP 3. Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral) 4. Haemophilus type B conjugate vaccine IP (Novohib) 5. Haemophilus type B conjugate vaccine BP (Novohib) 6. Easy Six™ purified	Dated 11th-12th July 2022 Drugs Inspectors of CDSCO, SLA and Subject Expert	Grant of CLAA approval of additional products namely adsorbed Diphtheria, Tetanus, pertussis, Poliomyelitis (Inactivated) and Haemophilus influenza Type b Conjugate vaccine IP in Form 28D	As per report	Observations communicated to the firm for compliance and to be verified in the follow up inspection	-	1st quarter annual inspection

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		Diphtheria Toxoid, Purified Tetanus Toxoid, Whole Cell Pertusis, Recombinant Hepatitis B, Haemophilus Influenza Type b conjugate and inactivated Poliomyelitis Trivalent vaccine (adsorbed) 7. Hepatitis B vaccine (rDNA) IP (Enivac HB) 8. Hepatitis B vaccine (rDNA) BP (Enivac FIB) 9. Diphtheria, Tetanus, Pertusis (Whole Cell) and Haemophilus influenza Type b conjugate vaccine (Adsorbed) IP (easy four-TT) 10. Gam-COVID-Vac, Combined vector vaccine, component-I (Sputnik V) 11. Gam-COVID-Vac, Combined vector vaccine, component-II (Sputnik V)						
2	M/s Panacea Biotech Ltd., Ambala Chandigarh Highway PO-Lalru Punjab 140501	1. Bulk Purified Diphtheria Toxoid (D) 2. Bulk Purified Tetanus Toxoid (T) 3. Whole cell Pertusis Bulk (wP)	28th to 29th June 2022 Drugs Inspectors of CDSCO, SLA	Renewal of GMP certificate for vaccine antigens bulk manufacturing facility and 2nd quarter annual inspection as per central inspection plan 2022	As per report	Observations communicated to the firm for compliance and to be verified in the	-	2nd quarter annual inspection & 4th quarter follow-up

Annexure-II of QMS-INS-002

"Format for Annual Central Inspection Plan for Vaccine Manufacturing Facilities"

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		4. Hepatitis B Vaccine (rDNA) IP (Bulk) 5. Hepatitis B Vaccine (rDNA) BP Bulk) 6. Hepatitis B Vaccine (rDNA) Bulk drug Substance 7. Haemophilus type b conjugate (PRP-TT) BP (Bulk) 8. Haemophilus influenza type b conjugated (PRP-TT) bulk (Indigenous)	and Subject Expert			follow up inspection		inspection

Remark:-

1. **This is a dynamic inspection plan and shall be updated as and when required**
2. **Inspections may be planned by Zonal/ Sub-Zonal offices as per the specific situation which may arise from time to time and the plan will be updated accordingly.**