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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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.	Serum Institute of India Pvt. Ltd. [S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114, 168-170 (M), Hadapsar, Pune 411028, District-Pune, State-Maharashtra, India -411028 **1. Hadapsar Facility, Pune, Maharashtra** **Facilities/Blocks/ Buildings planned for inspection and blocks:** 1. **Influenza Vaccine:** Bulk manufacturing at Building-3 (FF). 2. **Rotavirus Vaccine (FD & Liquid):** Bulk manufacturing at Building-5 (GF) and	Bacterial Vaccines, Viral Vaccines, rDNA Vaccines, Combination Vaccines	**18 to 20 December 2025 -3 Days** 1. DI, CDSCO (WZ-1), Mumbai, 2. DI, CDSCO (WZ-1), Mumbai, 3. FDA, Pune, 4. Expert, CDL Kasauli	Inspection as per Central Inspection Plan Quarter 4	As per the report	Observations communicated to the firm for compliance	Not reported	2nd Quarter (Hadapsar) 3rd Quarter (Hadapsar) 4th quarter (Manjari)

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	SEZ-4 (FF). 3. **Rabies Vaccine (FD):** Bulk manufacturing at SEZ-8 (SF). 4. **Hepatitis-B Vaccine:** Bulk manufacturing at Building-6 (FF) and SEZ-1B (SF – MMA-2). 5. **Meningococcal A Conjugate Vaccine:** Bulk manufacturing at SEZ-1B (SF). 6. **Meningococcal (A, C, Y, W, X) Vaccine:** Drug substance manufacturing at SEZ-3 (SF). 7. **Pneumococcal Conjugate Vaccine:** Bulk manufacturing at							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	SEZ-4 (SF) and SEZ-10 (TF). **1.2 Drug Product (D.P.) Facilities** 1. **Influenza Vaccine:** Blending, filling, and lyophilization at Building-3 (GF). 2. **Rotavirus Vaccine (FD):** Filling and lyophilization at SEZ-4 (GF). 3. **Rotavirus Vaccine (Liquid):** Filling and capping at Building-3 (GF), SEZ-4 (GF), and SEZ-9 (FF). 4. **Rabies Vaccine:** Filling and lyophilization at SEZ-1A (SF) and							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	SEZ-1B (GF). 5. **Hepatitis-B Vaccine:** Filling and capping at Building-6 (GF), SEZ-5 (GF), SEZ-6 (GF & FF), and SEZ-7 (FF). 6. **Meningococcal A Conjugate Vaccine:** Filling and lyophilization at SEZ-1B (GF), SEZ-1A (SF) and SEZ-4 (GF). 7. **Pneumococcal Conjugate Vaccine:** Formulation and filling at SEZ-7 (FF – Line-2 **2. Manjari Facility, Pune, Maharashtra**							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Facilities planned for inspection: **2.1 Drug Substance (D.S.) Facilities** 1. **SARS-CoV-2 rS Vaccine:** Drug substance manufacturing at M-SEZ-1 (GF & SF). **2. Tetanus, Diphtheria & aP Components:** Bulk component manufacturing at M-SEZ-1 (FF). 3. **BCG Vaccine / ONCO-BCG:** Drug substance manufacturing at M-SEZ-3 (GF).							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	4. **Rotavirus Vaccine:** Drug substance manufacturing at M-SEZ-3 (SF). 5. **Quadrivalent HPV Vaccine (qHPV):** Drug substance manufacturing at M-SEZ-4 (SF & TF). **2.2 Drug Product (D.P.) Facilities** 1. **SARS-CoV-2 rS & Cy-Tb Vaccines:** Drug product manufacturing, blending, filling and packing at M-SEZ-1 (GF). 2. **BCG Vaccine / ONCO-BCG:** Drug product manufacturing							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	at M-SEZ-3 (GF). 3. **Td Vaccine, Cy-Tb Vaccine & EPO:** Drug product manufacturing at M-SEZ-3 (FF).							
2.	M/s. Haffkine Bio-Pharmaceutical Corp Ltd., Acharya Donde Marg, Parel, Mumbai.	bOPV	**29 & 30 Sept.2025 -2 Days** 1. DI, CDSCO (WZ), Mumbai, 2. Drugs Inspector, CDSCO (WZ), Mumbai 3. DI, FDA, Gr. Mumbai. **03 .11.2025 to 06.11.2025** Inspection by the WHO team for verification of compliance with the previous PQ inspection.	Verification of compliance & restart of activities after modification. Verification of the compliance after the WHO PQ inspection	As per the report	The firm has submitted the interim progressive CAPA as of 02.11.2025	Not reported	2st Quarter & 4th Quarter
B	**North Zone**							
1.	M/s Bio-Med Pvt. Ltd. C-96, Site No. 1,	The following are the products approved by	**13.11.2025 and 14.11.2025.**	Routine joint inspection as	As per report	Observations communicated	Not reported	1st Quarter (Follow up

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Bulandshahr Road, Industrial area, Ghaziabad- 201009. Uttar Pradesh, India. 0120-4157534, 4159857/ 9818676886 E-mail: saryugarg@yahoo.com, bmvaccine@yahoo.com Website: www.biomed.co.in	CLAA & SLA on Form-28 D: A) Human Vaccines: 1. Poliomyelitis Vaccine, Live (Oral)I.P. Divalent (bivalent/bOPV) Packing-20 doses, glass& plastic. Manufacturing Permission has been suspended since 2018. 2. Typhoid Polysaccharide Vaccine I.P. (Brand Name –Bio TyphTM) Packing – One, Five, Ten & Twenty doses in glass vials. 3. Haemophilus Influenzae type b Conjugated Vaccine I.P. (Brand Name –Peda HibTM) Packing– One, Five, Ten doses in glass vials.	1. DI, CDSCO, NZ, Ghaziabad. 2. DI, CDSCO, NZ, Ghaziabad. 3. DI, Ghaziabad. 4. Expert, CDL Kasauli	per Central Inspection Plan 2025		to the firm for compliance.		Inspection) 3rd Quarter (Annual Inspection)

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		4. Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) I.P. (Brand Name – Quadri MeningoTM) Packing– One, Five & Ten doses in glass vials 5. Meningococcal Polysaccharide A & C Vaccine I.P. (Brand Name – BiMeningoTM) Packing– One, Five & and Ten doses in glass vials. 6. Polysaccharide Typhoid Vaccine (Brand Name – BioTyphTM) Packing – One, Five, Ten & twenty-doses in glass vials. 7. Haemophilus influenzae						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		Type b Conjugate vaccine (Brand Name – Peda HibTM) Dose- One, Five & Ten doses in glass vials. 8. Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) Brand Name – Quadri MeningoTM) Packing – One, Five & Ten doses in glass vials 9. Vi Conjugate Typhoid Vaccine (Brand Name- Peda TyphTM) Packing – Single, Five& Ten doses in glass vials. 10. Meningococcal Polysaccharide Vaccine (Group A &C) Bivalent. Dose–Single, five & ten doses in glass vials						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		11. Meningococcal Polysaccharide Vaccine (Group A &C) (Brand Name – BiMeningoTM) Packing– Single, five & ten doses in glass vials. 12. Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) Ph. Euro. Packing – Single, five, and ten doses in glass vials. 13. Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135) (Quadri MeningoTM) Brand Name - Nm Vac-4ACYW135, Packing – Single, five & and ten doses in glass vials.						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		14. Rabies Vaccine, Human I.P. (Brand Name – SURERABTM) Packing –Single, multi-dose in glass vial. 15. Varicella Vaccine (Live) I.P. Freeze-dried (Brand Name: Bio PoxTM) Packing – Single dose in glass vials. 16. Typhoid Polysaccharide Vaccine I.P. (Brand Name –Bio TyphTM) Packing – One dose in Prefilled Syringe. 17. Typhoid Vi Conjugate Vaccine I.P. (Brand Name-Peda TyphTM) Packing – one dose in Prefilled Syringe.						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
C	**East Zone**							
1	M/s Sapigen Biologix Private Limited, Plot No. B1/24 and ITBT 1/7, Odisha Biotech Park, Daspur Road, Mauza Andharua, Bhubaneswar, Kharodha, Odisha, 751003, India.	1. Bivalent Poliomyelitis vaccine Type 1 & 3 Live (Oral) I.P. 2. Rotavirus Vaccine [Live Attenuated, Oral] I.P.	**16/10/2025 & 17/10/2025** 1. DI, CDSCO.WZ-Mumbai 2. DI, CDSCO, Sub-Zone, Bhubaneshwar. 3. DI, DCA, Andhra Pradesh 4. Expert, CDL Kasauli	For Joint compliance verification of earlier joint inspection for Grant of WHO-GMP/COPP for Vaccine Products and grant additional products under the manufacturing License in Form-28D vide No. 896.	As per the report	Yes, Compliance met	Not reported	**2nd Quarter** Annual inspection **4th Quarter** Follow-up Inspection (if any)
D	**South Zone**							
1	M/s. Green Signal Biopharma 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/EP/IP/USP	**22.12.2025 to 24.12.2025** 1. DI, CDSCO.SZ-Chennai. 2. DI, SLA, Tamil Nadu 3. Expert, CDL Kasauli	Central Inspection Plan 2025 by using Risk-based approach.	As per report	Observations communicated to the firm for compliance and to be verified in the follow-up inspection	Not reported	4th quarter Follow-up Inspection
2	M/s Human Biologicals Institute (A division of Indian	1. Rabies Vaccine, Human IP, BP 2. Purified Rabies bulk	**08.12.2025 to 10.12.2025**	Annual inspection and follow-up inspection	As per report	Observations communicated to the firm for	Not reported	3rd quarter Follow-up

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Immunologicals Limited) Kozhipannai, Pudmund Post, Udhagamandalam – 643007, Tamil Nadu	antigen	1. DI, CDSCO.SZ-Chennai. 2. DI, SLA, Tamil Nadu 3. Expert, CDL Kasauli	of the earlier inspection.		compliance and to be verified in the follow-up inspection		Inspection
3	M/s. BCG Vaccine Lab, No. 110, 110A, 33 Feet Road, Mount Road, Guindy, Chennai-600032. Tamil Nadu	BCG Vaccine (Freeze-Dried) IP	**27.07.2024 to 31.07.2024** 1. DI, CDSCO.SZ-Chennai. 2. DI, SLA, Tamil Nadu 3. Expert, CDL Kasauli	Central Inspection plan 2024 by using Risk-based approach.	As per report	Observations communicated to the firm for compliance and to be verified in the follow-up inspection	Not reported	2nd quarter Follow-up Inspection
E	**<u>Hyderabad Zone</u>**							
1.	**M/s Biological E Limited,** Plot No.1, Phase-II, Biotech Park, Kolthur Village-500078, **Shameerpet**, Medchal-(D), Telangana **<u>Facilities planed for inspection:</u>** **<u>D.S. facilities:</u>**	D.S. & D.P. of the following vaccines Tetanus Vaccine, 1. DPT Vaccine, 2. Hepatitis B Vaccine, 3. Hexavalent Vaccine, 4. MR vaccine, 5. TCV, 6. CORBEVAX,	**21.07.2025 & 22.07.2025** 1. DI, CDSCO, Hyderabad. 2. DI, DCA, Telangana. 3. Expert, CDL Kasauli	For Grant of CT-11 for yellow fever vaccine, live attenuated (freeze-dried) D.S & D.P for CT purpose at Block- A (D.S) and filling line-4 (D.P).	As per the report	Firm Submitted CAPA closure report for all previous observations	Not reported	**1st Quarter** Annual inspection **4th Quarter** Follow-up Inspection (if any**)**

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Blending suites 2 &3 are used for the manufacturing of Pentavalent Vaccine & PCV-14 vaccine. **D.P. facilities:** Filling lines 1,2,3 involved in the manufacture of Pentavalent Vaccine & PCV-14 vaccine.	7. Pneumococcal 8. Polysaccharide 9. Conjugate Vaccine 10. (Adsorbed) (14 Valent) 11. PNEUBEVAX, 12. Haemophilus Type b Conjugate Vaccine B.P. (Lyophilized)						
2	**M/s Biological E Limited,** D. No. 7-4-34 Gagan Pahad, Rajendra Nagar (Mandal), R.R. Dist.., T.S. **Facilities planed for inspection:** **(Both Tetanus Block & Antisera Block)**	1. Tetanus Vaccine (Adsorbed) (Bulk), 2. Diphtheria Antitoxin 1000 I.U (Bulk), 3. Diphtheria Antitoxin 20000 I.U (Bulk), 4. Tetanus Antitoxin (Bulk)	**27.10.02025 & 28.10.2025** 1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	For Annul routine GMP inspection as per Central Inspection Plan-2025 based on a risk-based approach	As per the report	Observations communicated to the firm for compliance. To be verified in follow-up inspection.	Not reported	**3rd Quarter** Annual inspection **4th Quarter** Follow-up Inspection (if any**)**
3	**M/s. Human Biologicals Institute**	1. Inactivated Rabies Vaccine,	**03.11.2025 to 04.11.2025**	For Annul routine GMP inspection as	As per the	Observations communicated	Not reported	**3rd Quarter**

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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 division of Indian Immunologicals Limited, survey No.281 to 284 and 321, Karkapatla (V), Medak-Dist., 502281, TS **<u>Facilities planed for inspection:</u>** **D.S. manufacturing block in KH01** for Rabies vaccine Bulk & **D. P manufacturing block KH07** (Blending &Filling line for Rabies Vaccine)	2. Tetanus Vaccine.	1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	per the Central Inspection Plan-2025, based on risk-based approach	report	to the firm for compliance. To be verified in follow-up inspection.		Annual inspection **4th Quarter** Follow-up Inspection (if any**)**
4	**M/s. Bharat Biotech International Ltd.,** Genome Valley, Turkapally, Shameerpet (Mandal), Hyderabad-500078, T.S. **<u>Facilities planed for</u>**	1.Typhoid conjugate vaccine, 2.Rotavirus Vaccine, 3.Biopolio vaccine, 4. JE vaccine, 5.Hepatitis B Vaccine (recombinant), 6.Cholera Vaccine,	**12.11.2025 to 13.11.2025** 1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	for the grant of WHOGMP/COPP for the JE Vaccine	As per the report	Observations communicated to the firm for compliance. To be verified in follow-up inspection.	Not reported	**1st Quarter** Annual inspection **4th Quarter** Follow-up

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	inspection: D.S. manufacturing facilities: PA2 for COVID-19 Vaccine [ChAd36-SARS-CoV-2-S (Recombinant)] Bulk Drug Substance, PB3 for COVID-19 Vaccine [ChAd36-SARS-CoV-2-S (Recombinant)] Bulk Drug Substance, PB4 for Purified Bulk of Haemophilus influenzae Type bPRP, Purified Bulk of Haemophilus influenzae Type b-PRP-TT Conjugate vaccine. **D.P. manufacturing facilities**: filling line-1 of PA2 used for COVID-19 Vaccine	7.DPT, 8.Pentavalent Vaccine, 9.Covaxin, etc.						Inspection (if any**)**

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	[ChAd36SARS-CoV-2-S (Recombinant)]							
5	**M/s. Human Biologicals Institute,** (A Division of Immunological Limited) Rakshapuram, Gachibowli, Hyderabad-500019, T.S **<u>Facilities planed for inspection:</u>** **<u>D.S. manufacturing facilities:</u>** B8, B5, B9 blocks manufacturing Bulks of Tetanus Antigen (Up to Down Stream) Purification in B2 Block, Rubella	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). (Single dose 0.5 ml in a 2 ml vial and ten doses 5ml in a 5 ml vial). 3. Inactivated Hepatitis A Vaccine (Adsorbed) I.P. (for Domestic & Export) 4. Inactivated Hepatitis	**24.11.2025 to 26.11.2025** 1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	For the Grant of Form 28D to manufacture Pentavalent RTFB.	As per the report	Observations communicated to the firm for compliance. To be verified in follow-up inspection.	Not reported	**2nd Quarter** Annual inspection **3rd Quarter** Follow-up Inspection (if any**)**

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Antigen, Hepatitis A Antigen **<u>D.P. facilities</u>**: B5 block for Blending & filling of Hepatitis A vaccine, MR vaccine, and B11 (shared filling facility for various vaccines).	A Vaccine BP (1 ml vial, single adult dose/two pediatric doses), (for Export) 5. Measles and Rubella Vaccine (Live) I.P. (For Domestic & Export). 6. Measles and Rubella Vaccine (Live) (For Export). (0.5 ml single-dose vial and 2.5 ml multi-dose vial) 7. Hepatitis B vaccine (rDNA) I.P./B.P. (Liquid injectable multidose pediatric vaccine, 5 ml presentation)						
6	M/s. Dano Vaccines & Biological Pvt. Limited, 575, Sivareddyguda, Ghatkesar (M),	Tetanus Toxoid vaccine	**03-07-2025 & 04-07-2025** 1. DI, CDSCO,	For Annul routine GMP inspection as per the Central Inspection Plan-	As per the report	The firm submitted the CAPA closure report for all	Not reported	**2nd Quarter** Annual

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	R.R.Dist. – 501 302, T.S. (**Both D.S. & D.P. facilities of TT Vaccine).**		Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	2025, based on a risk-based approach		previous observations.		Inspection **4th Quarter** Follow-up Inspection (if any**)**
7	**M/s. Biological E. Limited,** 18/1 & 3, Azamabad, Hyderabad, T.S. **Facilities planed for inspection**: **Line-1** 1. Tetanus Vaccine (Adsorbed) I.P. 0.5 mL Ampoule, 2. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents 0.5mL Ampoules) **Line-2**	1. Tetanus Vaccine (Adsorbed), 2. DTP Vaccine (Adsorbed), 3. DT Vaccine (Adsorbed), 4. Tetanus Antitoxin, 5. Diphtheria antitoxin, 6. JE Inactivated Vaccine Bulk. Etc.	**29.10.2025 & 30.10.2025** 1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	For Annul routine GMP inspection as per Central Inspection Plan-2025, based on a risk-based approach	As per the report	Observations communicated to the firm for compliance. To be verified in follow-up inspection.	Not reported	**2nd Quarter** Annual Inspection **4th Quarter** Follow-up Inspection (if any**)**

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	1. Tetanus Antitoxin B.P. (1500 IU/mL) 1 mL ampoules (with Thiomersal and for prophylactic use), 2. Tetanus Antitoxin B.P.,1000 IU/mL, 1.0 mL Ampoules (With Cresol), Adsorbed Tetanus Vaccine B.P. 0.5 mL Ampoule, 3. Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents 0.5mL Ampoules.							
8	**M/s. Biological E. Limited**, Sy. No: 549, 550, 552 to 556, Kolthur Village, **SEZ facility**, Shameerpet, Medchal-Malkajgiri (D), Telangana-500078.	1. Pneumococcal conjugated vaccine (14-valent) [Five Dose] 2. MR vaccine, 3. Hepatitis B Vaccine 4. Tetanus Vaccine,	**26.06.2025 & 27.06.2025** 1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad	For Annul routine GMP inspection as per the Central Inspection Plan-2025, based on a risk-based approach	As per the report	Firm Submitted CAPA closure report for all previous observations.	Not reported	**1st Quarter** Annual Inspection **2nd**

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Facilities planed for inspection: Blending suite 4, filling line-4 involved in the manufacture of PCV-14 vaccine, and blending suite-2,3 filling line-2 involved in the manufacture of Covid-19 vaccine.	5. DPT vaccine, etc.	3. Expert, CDL Kasauli					**Quarter** Follow-up Inspection (if any)
9	M/s GCBC Vaccines Pvt Ltd, Survey. No 274, Athvelly Village, Medchal Mandal, Malkajgiri District, Hyderabad, Telangana, India 501401, India. **Facilities planed for inspection:** D.S. facilities suite B & C used for	1. FP & Bulk Vaccines (in vial) Inactivated Bivalent (o1 & O 139) 2. Oral Cholera Final Bulk Vaccine (RTFB), Oral Cholera 3. Bulk Vaccine, 4. Tetanus Bulk Purified toxoid I.P. 5. Diphtheria Bulk Purified Toxoid I.P.	**06.11.2025 & 07.11.2025** 1. DI, CDSCO, Hyderabad 2. DI, DCA, Hyderabad 3. Expert, CDL Kasauli	For the grant of the WHO-GMP/COPP for cholera vaccine Inactivated Oral I.P	As per the report	Firm Submitted CAPA closure report for all previous observations	Not reported	**3rd Quarter** Annual Inspection **4th Quarter** Follow-up Inspection (if any)

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	manufacturing of Diphtheria toxoid Bulk and Tetanus toxoid Bulk.							
F	**Ahmedabad Zone**							
1.	M/s.Zydus Life Sciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417,419 & 420, Sarkhej - Bavla N. H.No. 8A, Village: Moraiya, Tal. Sanand, Dist. Ahmedabad Gujarat-- 382 210, **Inactivated Viral Vaccine. DS – 1 Facility: Dedicated single product facility-**	1. Rabies Vaccine — VaxiRab N (Purified Chick Embryo Cell Culture Rabies Vaccine (PCECY™)	**03.04.2025 to 05.04.2025** 1. Sr. Drug Inspector, FDCA Gujarat, Ahmedabad Rural Circle 2. Drug Inspector, CDSCO Ahmedabad Zone 3. Drug Inspector, CDSCO Ahmedabad Zone 4. Assistant Technical Officer, CDL-Kasauli | - (Through Virtual Mode)	CIP Plan Using Risk-Based Approach for the year 2025.	As per the report	17.11.2025 Desktop Compliance Verification	Not reported	1st Quarter

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Bulk of Inactivated Rabies Vaccine, Human I.P. **Vaccine R, Pharma Block, Fill finish facility: Dedicated single product facility -** Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV^{PM}]							
2.	M/s Chiron Behring Vaccines Pvt. Ltd., Plot No. 3502, G.I.D.C. Estate, P. B. No. 136, Ankleshwar, Dist.: - Bharuch - 393002, Gujarat Drug Substance: 1 Block Drug Product: 2	1. Rabies Vaccines for Human Use (ChiroRab®)	**23.06.2025 to 25.06.2025** 1. Senior Drug inspector, FDCA Bharuch, Gujarat 2. Technical Officer, CDL Kasauli 3. Drugs Inspector CDSCO, Ahmedabad 4. Drugs Inspector,	Central Inspection Plan Using Risk Based Approach for the year - 2025.	As per report	Observations have been communicated to the firm for compliance and compliance yet to be verified	Not reported	2nd Quarter

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Blending and Filling Lines Commercial Product: Rabies Vaccines for Human Use. Under Development Product against Test License: 1. Malaria Vaccine (Drug Product in filling Line-2) 2. Monkey Pox (Drug Substance under development) 3. Yellow Fever Vaccine (Drug substance Development to be Initiated)		CDSCO, Ahmedabad					
3.	M/s Cadila Pharmaceuticals	1. Recombinant Rabies	**29.09.2025 to 01.10.2025**	Central Inspection Plan Using Risk-	As per the report	Observations have been	Not reported	3rd Quarter

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Limited, 1389, Dholka - 382 225, Dist. Ahmedabad, Gujarat **DS Manufacturing Facility:** **Multi-product facility-** 1. Monovalent Influenza A (H1N1 2009) Virus-Like Particles (VLPs) Vaccine 2. Trivalent Seasonal Influenza Virus-Like Particles (VLPs) Vaccine 0.5 ml Vial 3. 3. Recombinant Rabies G Protein Vaccine 2 ml Glass Vial 4. "Quadrivalent Seasonal Influenza VLP Vaccine."	G Protein Vaccine (Thrabis) 2. Quadrivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine 3. Cadiflu-S (Trivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine) 4. Monovalent Influenza A (H1N1 2009) Virus-like Particle (VLPs)-Vaccine 0.5ml Vial-Cadiflu	1. Drugs Inspector, FDCA, Ahmedabad (Rural) Gandhinagar, Gujarat State 2. Drugs Inspector, CDSCO, Ahmedabad 3. Drugs Inspector, CDSCO, Ahmedabad. 4. CDL, Kasauli, HP	Based Approach for the year 2025.		communicated to the firm for compliance, and compliance is yet to be verified		

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	DP Filling facility: Multi-product facility- Main Pharma Building							
4.	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. Ahmedabad - 382 213, Gujarat **Plant 3A: Multi-product facility-**	1. Inactivated Influenza Vaccine (Split Virion) LP. (Tetravalent) (0.5 ml), HIN1 Inactivated Influenza Vaccine (Whole Virion), 2. Typhoid Polysaccharide Vaccine, 3. Typhoid Vi Conjugate Vaccine LP., 4. Measles, Mumps and Rubella Vaccine, 5. Measles Vaccine,	**19.11.2025 to 20.11.2025** 1. Senior Drug inspector, FDCA Gandhinagar 2. Drugs Inspector, CDSCO, Ahmedabad 3. Drugs Inspector CDSCO, Ahmedabad 4. 4.Assistant Technical Officer, CDL Kasauli	For Grant of WHO-GMP certificate	As per report	Observations have been communicated to the firm for compliance and compliance yet to be verified	Not reported	4th Quarter

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	• Bulk purified Diphtheria Toxoid - Drug Substance • Whole cell Pertussis bulk- Drug Substance **Fill finished vaccine facility (SVP-1):** **Plant 3B- Multi-product facility** **Formulation and Filling:** • Typhoid Polysaccharide Vaccine I.P. • Typhoid Vi Conjugate Vaccine	6. Varicella Vaccine, 7. Measles & Rubella Vaccine (Live) LP. (Freeze Dried), 8. Tetanus Vaccine (Adsorbed) LP., 9. Diphtheria, Tetanus & (Whole Cell) Pertussis Vaccine (Adsorbed) LP. 10. Novel Corona Virus 2019-nCoV Vaccine is manufactured at the site with special permission as per Form 28D.						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	I.P. • Tetanus Vaccine (Adsorbed) I.P. • Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P. • Diphtheria, Tetanus and Pertussis (Whole cell) Vaccine (Adsorbed) I.P. **Live Viral Vaccine Production:** **Plant 4- Dedicated suites for different Drug substance.** • Virus Suite I- Clarified Measles							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Single Harvest (Bulk) – Drug Substance • Virus Suite II- Clarified & concentrated Mumps (Bulk) – Drug Substance • Virus Suite III- Clarified and Concentrated Rubella Single Harvest (Bulk) – Drug Substance • Virus Suite IV- Single Harvest / Concentrated bulk of Varicella Vaccine (Live) – Drug Substance **Fill finished vaccine**							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	facility (SVP – 2): **Plant 5- Multi-product facility** **Formulation and Filling:** • Measles Vaccine (Live) I.P. (Freeze Dried) • Measles and Rubella Vaccine (Live) I.P. (Freeze Dried) • Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) • Varicella Vaccine (Live) I.P. (Freeze Dried)							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Inactivated Viral Vaccine Production: **Plant 6A & Plant 6B- Multi-product facility-** • Inactivated Sterile Bulk (Split Virion, H1N1) • Inactivated Sterile Bulk (Split Virion, H3N2) • Inactivated Sterile Bulk (Split Virion, Type B Victoria lineage) • Inactivated Sterile Bulk (Split Virion, Type B Yamagata lineage)							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	• Formulation of Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) **Fill Finish Vaccine Facility (SVP-3):** **Plant 8- Multi-product facility** **Fill and Finish:** • Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) • Novel Corona Virus 2019-nCoV vaccine							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	(Recombinant) • Typhoid Polysaccharide Vaccine I.P. • Typhoid Vi Conjugate Vaccine I.P. **Viral Vaccine Production:** **Plant 13A- Dedicated suites for different Drug substances.** • Clarified Measles Single Harvest (Bulk) – Drug Substance • Clarified and Concentrated Rubella Single							

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Harvest (Bulk) – Drug Substance							
G	**Baddi Zone**							
1.	M/s. Panacea Biotec Limited, Village Malpur, Baddi, Distt. Solan (H.P).	1. Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA), and Haemophilus influenza Type b conjugate vaccine (Adsorbed) IP (Easy five-TT). 2. Diphtheria, Tetanus & Pertussis vaccine (adsorbed) IP. 3. Bivalent Poliomyelitis Vaccine Type 1 & Type 3, Live (Oral) (P.T. Biofarma Indonesia).	Dated: 26/03/2025 to 27/03/2025 Team: 1. Drug Inspector, CDSCO, Baddi Zone 2. Drug Inspector, Baddi, SLA H.P. 3. Asst. Technical Officer, CDL Kasauli	1st Quarter annual inspection as per Central Inspection Plan 2025	As per report	NA	Not reported	**1st Quarter** Annual Inspection

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		4. Haemophilus type B conjugate vaccine IP (Novohib). 5. Haemophilus type B conjugate vaccine BP (Novohib). 6. EasySix™ purified Diphtheria Toxoid, Purified Tetanus Toxoid, Whole Cell Pertussis, Recombinant Hepatitis, Haemophilus Influenza Type b conjugate, and inactivated Poliomyelitis Trivalent vaccine (adsorbed). 7. Hepatitis B vaccine (rDNA) IP (Enivac						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		HB). 8. Hepatitis B vaccine (rDNA) BP (Enivac HB). 9. Diphtheria, Tetanus, Pertussis (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) 12. Easy-Four Pol (purified Diphtheria						

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		Toxoid,)						
2.	M/s. Panacea Biotec Limited, 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) 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)	**06.11.2025 and 07.11.2025** 1. Drugs Inspector, CDSCO Baddi Zone, 2. Drug Inspector, FDA Punjab, 3. Asst. Technical Officer, CDL Kasauli	3rd Quarter annual inspection as per Central Inspection Plan 2025	As per the Report	Compliance report awaited	Not reported	**3rd Quarter** Annual Inspection

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
		8. Haemophilus Influenza type b conjugated (PRP-TT) Bulk (Indigenous)						
3	M/s Central Research Institute, Kasauli, H.P.	1. Diphtheria, Tetanus & Pertussis Vaccine (Adsorbed). 2. Concentrated Diphtheria, Tetanus Pertussis Vaccine (Adsorbed), 3. Tetanus vaccine (Adsorbed), 4. Diphtheria & Tetanus Vaccine (Adsorbed).	The manufacturing unit is under renovation.	NA	NA	NA	Not reported	**1st Quarter** Annual Inspection & **4th Quarter** Follow-up inspection
G	**Indore SZ**							
1	M/s. Bio Vaccines (India) Pvt. Ltd., 46-A, Sanwar Road Industrial	1. Tetanus Vaccine (Adsorbed) IP 0.5ml	**23.09.2024 &**	Risk-based annual inspection as per the	As per the report	Desktop Compliance	Not reported	Sep 2026

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

Central Inspection Plan of Vaccine Manufacturing Units for 2026 using Risk-Based Approach

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
	Area, Indore-452015	Ampoule (Single Dose Ampoule) 2. Tetanus Vaccine (Adsorbed) IP 5.0 ml Vial (Ten Dose Vial)	**24.09.2024** 1. Drugs Inspectors CDSCO Sub Zone Indore, 2. Drugs Inspectors CDSCO Sub Zone Indore 3. Drugs Inspector, FDA MP	central inspection plan.		verification was done on 10.06.2025, and the firm was found to comply with applicable WHO-TRS and the Scheduled M of Drugs Rules.		

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.

3. Six facilities were licenced to manufacture the COVID-19 vaccine. Presently, these facilities are not operational and not included in the CIP

4. One site is not included as per the risk assessment.

5. One site is not included as it is presently not operational.