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S. No.	Date of Inspection	Purpose of Inspection	Team of Inspector / Expert	Remarks / Conclusions	Regulatory Actions (Certification and/or Enforcement)
A.	**M/s Zydus Lifesciences Limited (formerly Cadila Healthcare Ltd.), Survey No. 417, 419 & 420, Sarkhej-Bavla N.H. No. 8A, Village: Moraiya, Tal. Sanand, Dist. Ahmedabad - 382 210, Gujarat**				
1.	03.04.2025 to 05.04.2025	Routine inspection under CIP 2024.	Team comprising officers from CDSCO, State, and CDL Kasauli.	The joint inspection of the firm was carried out from 03.04.2025 to 05-04-202505. During inspection, certain minor observations were noted with respect to the facility, validation, Quality Risk Assessment, and documentation	The firm was directed to submit compliance with respect to the observations noted during inspection.
B.	**M/s Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka, Dist.: Ahmedabad - 382225, Gujarat**				
1.	29.09.2025 to 01.10.2025	Routine inspection under CIP 2024.	Team comprising officers from CDSCO, State, and CDL Kasauli.	The joint inspection of the firm was carried out from 29.09.2025 to 01.10.2025. During inspection, certain observations were noted with	The firm was directed to submit compliance with respect to observations noted during inspection.

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				respect to procedure and process and adherence to SOPs.	
C.	**M/s Zydus Lifesciences Limited, Survey No. 23, 25/P, 37, 40/P, 42-47, 49 & 50, Sarkhej-Bavla N.H. No. 8A, Village: Changodar, Tal. Sanand, Dist. Ahmedabad - 382 213, Gujarat**				
1.	19.11.2025 to 20.11.2025	Joint inspection for the grant of COPP renewal under the WHO-GMP Certification Scheme.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Inspection carried out for COPP renewal under the WHO-GMP Certification Scheme. Observations noted with respect to storage, validation, quality control, and manufacturing.	The firm was directed to submit compliance with respect to the observations noted during inspection. The compliance of the observations submitted by the firm as CAPA was verified.
D.	**M/s Chiron Behring Vaccines Pvt. Ltd., Plot No. 3502, G.I.D.C. Estate, P.B. No. 136, Ankleshwar, Dist: Bharuch - 393002, Gujarat**				
1.	23.06.2025 to 25.06.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	The joint inspection of the firm was carried out from 06.06.2024 & 07.06.2024 for the grant of CPP as per WHO guidelines. During	The firm has complied with all observations. Compliance was found satisfactory.
E.	**M/s. Human Biologicals Institute (A Division of Immunological Limited), Rakshapuram, Gachibowli, Hyderabad - 500019, Telangana**				
1.	07.04.2025 & 08.04.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks forwarded to CDSCO (HQ) & SLA vide Hyd-12011(27)/4/2025-eoffice dated 28.04.2025	The compliance of the observations submitted by the

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					firm as CAPA was verified, and the CAPA Closed
2.	24.11.2025 to 26.11.2025	For the grant of a manufacturing licence in Form 28D	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	The firm was directed to submit compliance with respect to the observations noted during inspection.
3.	24.11.2025 to 26.11.2025	For the grant of a manufacturing licence in Form 28D	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA.	The firm was directed to submit compliance with respect to the observations noted during inspection.
F.	**M/s Biological E Limited, 18/1 & 3 Azamabad, Hyderabad - 500 020, Telangana, India**				
1.	29.10.2025 & 30.10.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
G.	**M/s Biological E Limited - Drug Substance, 7-4-114, Gaganpahad, Ranga Reddy District, Telangana**				
1.	27.10.2025 & 28.10.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	The firm was directed to submit compliance with respect to the observations noted during the inspection
H.	**M/s. Dano Vaccines & Biological Pvt. Limited, 575, Sivareddyguda, Ghatkesar (M), R.R. Dist. - 501 302, Telangana**				

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1.	03.07.2025 & 04.07.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	The firm was directed to submit compliance with respect to the noted observations.
2.	05.12.2025	CAPA verification dated 03.07.2025 & 04.07.2025 for routine inspection under CIP 2025.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with a direction to the firm to submit CAPA	CAPA to be submitted by the firm for verification
I.	**M/s Biological E Limited, Plot No. 1, Phase-II, Biotech Park, Kolthur Village - 500078, Shameerpet, Medchal-Malkajgiri (D), Telangana**				
1.	03.04.2025 & 04.04.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks forwarded to CDSCO (HQ) & SLA with a direction to the firm to submit CAPA	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
2.	08.05.2025 & 09.05.2025	Joint inspection for the grant of a license in form 28D for an additional product.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks forwarded to CDSCO (HQ) & SLA with a direction to the firm to submit CAPA	CAPA Closed
3.	03.07.2025 & 04.07.2025	For the grant of permission in Form CT 11 for examination, test, and analysis.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	CAPA Closed

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4.	21.07.2025 & 22.07.2025	For the grant of permission for WHO-GMP/COPP as per the WHO guidelines.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
5.	08.08.2025	CAPA verification for inspection dated 03.04.2025 & 04.04.2025 for routine inspection under CIP 2025.	Team comprising officers from CDSCO, State, and CDL Kasauli.	The firm has rectified all pending deficiencies	The firm was directed to submit compliance with respect to the noted observations.
J.	**Biological E. Limited - SEZ Site, Sy. No. 549, 550, 552-556, Kolthur Village, Shameerpet, Telangana (Drug Product)**				
1.	03.04.2025 & 04.04.2025	Joint inspection for the grant of a license in Form 28D.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks of JIR forwarded to CDSCO (HQ) & SLA vide Hyd-12011(21)/4/2025-eoffice dated 28.04.2025	The firm was directed to submit a CAPA with respect to the noted observations
2.	26.06.2025 & 27.06.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	The firm was directed to submit a CAPA with respect to the noted observations
3.	29.12.2025-31.12.2025	For the grant of Form 28D licence	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	CAPA to be submitted by the firm for verification

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4.	29.12.2025-31.12.2025	For the grant of COPP	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	CAPA to be submitted by the firm for verification
K.	**M/s Bharat Biotech International Ltd., Sy. No. 230, 231 & 235 Genome Valley, Turkapally Village, Shameerpet Mandal, Medchal-Malkajgiri Dist. - 500 078, Telangana State, India**				
1.	10.03.2025 & 11.03.2025	Joint Inspection for the grant of a manufacturing licence in Form 28D	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks of JIR forwarded to CDSCO (HQ) & SLA vide Hyd-12011(21)/1/2025-eoffice dated 27.03.2025	CAPA Closed. Recommended for the grant of Form 28D.
2.	13.05.2025, 14.05.2025 & 15.05.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks forwarded to CDSCO (HQ) & SLA vide Hyd-12011(21)/7/2025-eoffice dated 21.05.2025	The firm was directed to submit compliance with respect to pending observations.
3.	21.08.2025 to 22.08.2025	For the grant of permission in Form CT 11 for the manufacture.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to the firm to submit CAPA; copy forwarded to CDSCO (HQ) & SLA	The firm was directed to submit compliance with respect to the noted observations.
4.	11.08.2025	For the grant of permission in Form CT-11	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to the firm to submit CAPA; copy forwarded to CDSCO (HQ) & SLA	The firm was directed to submit compliance with respect to the noted observations.
5.	31.10.2025	CAPA verification dated 21.08.2025 & 22.08.2025 for	Team comprising officers from CDSCO, State, and CDL Kasauli.	The firm complied with all observations noted during the earlier audit. Recommended for grant of	The compliance of the observations submitted by the

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		routine inspection under CIP 2025.		CT-11 vide Hyd-12011(20)/13/2025-eoffice dated 20.11.2025	firm as CAPA was considered acceptable.
6.	13.10.2025 to 15.10.2025	CAPA verification dated 10.03.2025 to 12.03.2025 for routine inspection under CIP 2025.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	Updated CAPA to be submitted by the firm for verification
7.	13.10.2025 to 15.10.2025	CAPA verification dated 13.05.2025 to 15.05.2025 for routine inspection under CIP 2025.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	Updated CAPA to be submitted by the firm for verification
8.	12.11.2025 & 13.11.2025	For the grant of permission for WHO-GMP/COPP as per the WHO guidelines.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	CAPA Closed
L.	**M/s. GCBC Vaccines Private Limited (previously M/s. Sanofi Healthcare India Pvt Limited), Survey No. 274, Athvelly Village, Medchal Mandal, Medchal Malkajgiri District, Hyderabad, Telangana - 501401**				
1.	08.05.2025 & 09.05.2025	For the grant of a manufacturing licence in Form 28D.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks forwarded to CDSCO (HQ) & SLA vide Hyd-1201(21)/8/2025-eoffice dated 13.05.2025	The firm was directed to submit compliance with respect to observations noted during inspection.

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2.	06.11.2025 & 07.11.2025	For the grant of the WHO-GMP/COPP certificate	Team comprising officers from CDSCO, State, and CDL Kasauli.	Firm directed to submit compliance with respect to the observations noted during the inspection.	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
M.	**M/s. PopVax Private Limited, C1, Block No. 3, 3rd Floor, IDA, IP Uppal, Medchal-Malkajgiri District - 500039, Hyderabad, Telangana, India**				
1.	15.09.2025 & 16.09.2025	For the grant of permission in form CT-11 to manufacture for examination, test, and analysis.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to the firm to submit CAPA; a copy of the same was forwarded to CDSCO (HQ) & SLA	The firm was directed to submit compliance with respect to observations noted during inspection.
2.	17.11.2025	CAPA verification for joint inspection dated 15.09.2025 & 16.09.2025 for routine inspection under CIP 2025.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Updated CAPA verified and closed.	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
N.	**M/s. Human Biologicals Institute, Survey No. 281 to 284 and 321, Biotech Park Phase-III, Karkapatla Village, Mulugu Mandal, Siddipet, Telangana**				
1.	05.04.2025	Investigation of facts regarding counterfeit drugs	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks of JIR forwarded to CDSCO (HQ) & SLA vide Hyd-15011(11)/11/2025-eoffice dated 07.04.2025	The firm was directed to submit a CAPA with respect to the noted observations

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2.	15.04.2025 to 17.04.2025	For the grant of COPP as per the WHO-TRS Guidelines and revised Schedule M — 1.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Remarks of JIR forwarded vide Hyd-12012(11)/19/2025-eoffice dated 28.04.2025	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
3.	08.09.2025 & 09.09.2025	Joint inspection for the grant of a license in form 28D for an additional product.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to the firm to submit CAPA; copy forwarded to CDSCO (HQ) & SLA	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
4.	03.11.2025 & 04.11.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Deficiencies communicated to CDSCO (HQ) & SLA with direction to the firm to submit CAPA	CAPA to be submitted by the firm for verification
5.	03.11.2025	CAPA verification for inspection dated 25.09.2025 & 26.09.2025 for routine inspection under CIP 2025.	Team comprising officers from CDSCO, State, and CDL Kasauli.	The firm complied with all observations noted during the earlier audit dated 25.09.2025 to 26.09.2025	The compliance of the observations submitted by the firm as CAPA was considered acceptable.
O.	**M/s. Bio Vaccines (India) Pvt. Ltd., 46-A, Sanwar Road Industrial Area, Indore - 452015, Madhya Pradesh**				
1.	18.03.2024	Compliance verification for inspection dated 01.03.2023 to	Team comprising officers from CDSCO, State, and CDL Kasauli.	The compliance of the observations submitted by the firm as CAPA was verified through joint inspection on 18.03.2024.	The compliance of the observations submitted by the firm as CAPA was considered acceptable.

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		03.03.2023 and 28.06.2023 for routine inspection under CIP 2023			
P.	**M/s Haffkine Bio-Pharmaceutical Corporation Ltd., Acharya Donde Marg, Parel, Mumbai - 411012, Maharashtra**				
1.	18.09.2025 & 19.09.2025	Joint inspection for verification of compliance of the WHO prequalification inspection dated 12.06.2023-16.06.2023 and the joint inspection dated 20.12.2023-22.12.2023.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Firm submitted updated ongoing compliance/CAPA for 14 observations. Points no. 1, 2, 5, 8, 9, 10, 11, 12, 13, and 14 are still ongoing and require further addressing.	The firm was directed to submit compliance with respect to open observations noted during the inspection.
Q.	**M/s Serum Institute of India Pvt. Ltd., S. No. 105-110, Manjari Bk., Pune 412 307, Maharashtra**				
1.	18.09.2025 & 19.09.2025	Joint inspection for the grant of CoPP for additional products & permission to use the new QC	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to Stability data, technology transfer, Good housekeeping and safety, qualification, AMV, and premises.	The firm was directed to submit compliance with respect to observations noted during the inspection.

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		Laboratory MSEZ-3A ground floor.			
2.	27.11.2025 & 28.11.2025	Joint inspection for the grant of COPPs for 4 additional products.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to process qualification, change controls, and technology transfer.	The firm was directed to submit compliance with respect to observations noted during inspection.
R.	**M/s. Serum Institute of India Ltd., S. No. 212/2, Hadapsar, Pune - 411028, Maharashtra**				
1.	20.01.2025 & 21.01.2025	Joint inspection for the grant of permission to use the new facility	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to the site master file, validation master plan, production, and quality control testing procedures.	The firm was directed to submit compliance with respect to observations noted during inspection.
2.	24.03.2025 to 26.03.2025	Joint inspection for the grant of permission to use the new facility	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to transport validation, aseptic media simulation, and Equipment Qualification.	The firm was directed to submit compliance with respect to observations noted during inspection.
3.	07.05.2025	Joint Investigation for voluntary recall of Inactivated Polio Vaccine (IPV) 10 Dose from the Philippines and Thailand market	Team comprising officers from CDSCO, State, and CDL Kasauli.	Verified records, documents related to the import of bulk & export of vaccine, testing records, and control samples during the investigation.	The firm was directed to submit compliance with respect to the observations noted during inspection.

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4.	08.09.2025 & 09.09.2025	Joint inspection for permission to manufacture a new Viral Vaccine	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations noted with respect to Change control, Tech transfer, Site Master File, post approval change, and Equipment Qualification.	The firm was directed to manufacture & ensure early closure of ongoing investigation at Bilthoven Biologicals, completion of voluntary recall, reconciliation, and destruction of impugned batches; implement active safety surveillance of IPV batches in the Philippines & Thailand.
5.	18.12.2025 to 20.12.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to reconstitution of freeze-dried vaccines, cycle time of the dynamic pass box, and complaint handling.	The firm was directed to submit compliance with respect to the observations noted during the inspection.
S.	**M/s Panacea Biotec Ltd., Ambala-Chandigarh Highway, Lalru, Distt. Mohali, Punjab**				
1.	10.02.2025 to 11.02.2025	Joint inspection for grant of permission in Form CT-11 for clinical trial purposes.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Inspection conducted at the Vaccine Bulk Manufacturing Facility. Certain observations were noted.	The firm was directed to submit compliance with respect to observations noted during the inspection.
T.	**M/s Panacea Biotec Ltd., Village Malpur, Baddi, Distt. Solan, H.P.**				
1.	26.03.2025 to 27.03.2025	Joint inspection for the grant of an	Team comprising officers from CDSCO, State, and CDL Kasauli.	Inspection conducted for the grant of an additional product licence in Form	The firm was directed to submit compliance with respect to the

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		additional product licence in Form 28-D		28-D. Certain observations were noted.	observations noted during the inspection.
U.	**M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Kozhipannai, Pudumund Post, Udhagamandalam-643007, Tamil Nadu**				
1.	08.12.2025 to 10.12.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to quality control, validation, and documentation.	The firm was directed to submit compliance with respect to observations noted during the inspection.
V.	**M/s. Green Signal Bio Pharma Limited, No. 49, Pappankuppam Village, Gummidipoondi, Chennai-601 201, India**				
1.	29.04.2025 & 30.04.2025	For issuance of CoPP as per WHO guidelines.	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted with respect to storage, validation, and manufacturing.	The application may be considered with direction to rectify observations noted during inspection.
2.	22.05.2025 & 24.05.2025	Investigation of OOS reported by the WHO contract testing labs.	Team comprising of officers from CDSCO, State and CDL Kasauli.	No deviations found in the manufacturing and testing procedures of said batches for the OOS reported.	The investigation report was forwarded to CDSCO (HQ) for further necessary action.
3.	17.11.2025 to 19.11.2025	Joint inspection for Pharmacovigilance (Human Vaccines).	Team comprising officers from CDSCO, State, and CDL Kasauli	Firm found to lack an adequate system for passive surveillance for spontaneous reporting. Observations noted.	The firm was directed to submit compliance w.r.t the noted observation.
4.	22.12.2025 to 24.12.2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO,	Observations noted with respect to Materials, OOS, Self-inspections, training, GMP in quality control,	The firm was directed to submit compliance within 30 days.

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			State, and CDL Kasauli.	Media simulation studies, and labels.	
W.	**M/s. Bio-Med Pvt, C-96, Site No.1, Bulandshahr, Road Indl Area, Ghaziabad**				
1.	13-11-2025 & 14-11-2025	Routine inspection under CIP 2025	Team comprising officers from CDSCO, State, and CDL Kasauli.	Certain observations were noted in the Inspection Report. The manufacturer requested a response to all observations with a description of corrective actions and target dates. For 'major' observations, supporting documentation is to be submitted as objective evidence.	The firm was directed to submit compliance; an on-site follow-up inspection was planned to verify effective implementation of corrective actions.