

Annexure – VIII(b)
Details of GMP inspection 2024

S. No.	Date of Inspection	Purpose of inspection	Team of inspector/ Expert	Remarks/ Conclusions	Regulatory actions (certification and/or enforcement)
A.	M/s Serum Institute of India Pvt Ltd, S. No. 212/2, Hadapsr, Pune 411 028, Maharashtra.				
1.	08.01.2024 to 10.01.2024	Joint inspection for NOC to manufacture for Export Purpose.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 08.01.2024 to 10.01.2024 for the purpose of NOC to manufacture for Export Purpose. During inspection certain observations were noted with respect to storage, validation, quality control and manufacture etc.	Firm was directed to submit compliance with respect to the observations noted during inspection.
2.	02.05.2024 to 03.05.2024	Joint inspection for addition of new manufacturing facility.	Team comprising of officers from CDSCO and State.	The joint inspection of the firm was carried out from 02.05.2024 to 03.05.2024 for the purpose of addition of new manufacturing facility. During inspection certain minor observations were noted with respect to facility, validation, Quality Risk Assessment and documentation.	1. Firm was directed to submit compliance with respect to the observations noted during inspection. 2. Post approval change NOC issued for the proposed change.

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S. No.	Date of Inspection	Purpose of inspection	Team of inspector/ Expert	Remarks/ Conclusions	Regulatory actions (certification and/or enforcement)
3.	22.07.2024 to 24.07.2024	Joint inspection for grant of CPP as per WHO guidelines and Routine Joint inspection under Central Oversight of Central Inspection Plan-2024.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 22.07.2024 to 24.07.2024 for the purpose of grant of CPP as per WHO guidelines. During inspection certain observations were noted with respect to material management, quality control, manufacturing process and control, Validation and documentation.	1. Firm was directed to submit compliance with respect to the observations noted during inspection. 2. The compliance of the observations submitted by the firm as CAPA were verified through desktop review on.13.08.2024 and was considered as acceptable 3. Grant of CPP was recommended.
4.	18.12.2024 to 20.12.2024	Routine Joint inspection under Central Oversight of Central Inspection Plan-2024	Team comprising of officers from CDSCO and State.	The joint inspection of the firm was carried out from 18.12.2024 to 20.12.2024 for the purpose of routine inspection as per CIP 2024. During inspection certain observations were noted with respect to specification,	The firm is meeting the minimum requirements of Schedule M and Schedule L-I of Drugs Rules, 1945 and applicable WHO guidelines & the firm is operating at an

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				SOPs etc.	acceptable level of compliance with GMP guidelines
B.	M/s Serum Institute of India Pvt Ltd, S. No. 105 – 110, Manjari Bk., Pune 412 307, India, Maharashtra, India				
1.	21.03.2024 to 22.03.2024	Compliance verification for inspection dated 20.05.2023.	Team comprising of officers from CDSCO and State	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection from 21.03.2024 to 22.03.2024.	1. Firm was directed to submit CAPA plan with respect to the remaining observations. 2. The compliance of the observations submitted by the firm as CAPA were verified through desktop review on.04.10.2024 and was considered as acceptable for grant of permission to manufacture.
2.	18.12.2024 to 20.12.2024	Routine inspection under CIP 2024.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 18.12.2024 to 20.12.2024 for the purpose of routine inspection as per CIP 2024. During inspection certain observations were noted	Firm was directed to submit compliance with respect to the observations noted during inspection.

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				with respect to procedure and process and adherence to SOPs.	
C.	M/s Gennova Biopharmaceuticals Limited, Block 1, Plot No. P-1 & P-2, ITBT park, Phase II, MIDC, Hinjawadi, Pune, Maharashtra, India				
1.	24.04.2024 to 26.04.2024	Routine inspection under CIP 2024.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 24.04.2024 to 26.04.2024 for the purpose of routine inspection as per CIP 2024. During inspection certain observations were noted with respect to procedure and process and adherence to SOPs.	1. Firm was directed to submit compliance with respect to the observations noted during inspection. 2. The compliance of the observations submitted by the firm as CAPA were verified through desktop review on.05.06.2024 and was considered as acceptable.
D.	M/s. Panacea Biotec Limited, Village Malpur, Baddi, Distt. Solan (H.P).				
1.	28.02.2024	Compliance verification for inspection dated 28.12.2023 to 30.12.2023 for routine	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection on 28.02.2024 in which most of the	Grant of CPP was recommended.

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		as per CIP 2023 and CPP as per WHO GMP		observations were found complied.	
2.	03.10.2024 to 04.10.2024	Routine Joint inspection under Central Oversight of Central Inspection Plan-2024	Team comprising of officers from CDSCO, State and CDL kasauli.	The joint inspection of the firm was carried out from 03.10.2024 to 04.10.2024 for the purpose of routine inspection as per CIP 2024. During inspection certain observations were noted with respect to manufacturing, SOPs etc.	Firm was directed to submit compliance with respect to the observations noted during inspection.
E.	M/s. Biological E Limited., Plot No. 1, SP Biotechnology Park, Phase-II, Kolthur Village, Shameerpet Mandal, R.R.Dist, T.S.				
1.	26.03.2024 to 28.03.2024	Joint inspection for grant of license in form 28D for additional product.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 26.03.2024 to 28.03.2024 for the purpose of grant of additional products manufacturing licence in Form 28D. During inspection certain minor observations were noted	Firm was directed to submit compliance with respect to the observations noted during inspection.

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				with respect to facility, validation, Quality Control and documentation.	
2.	22.05.2024	Compliance verification for inspection dated 26.03.2024 to 28.03.2024.	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection on 22.05.2024 in which most of the observations were found complied.	Licence to manufacture the applied vaccine under Form 28D granted.
3.	22.04.2024 to 24.04.2024	Joint inspection for Grant of permission in Form CT 11 for manufacture, examination, test and analysis.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 22.04.2024 to 24.04.2024 for the purpose of for grant of permission in Form CT 11 for manufacture, examination, test and analysis. During inspection minor observation was noted with respect to facility, quality management system and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.

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4.	20.06.2024 to 21.06.2024	Compliance verification for inspection dated 22.04.2024 to 24.04.2024	Team comprising of officers from CDSCO and State	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection from 20.6.2024 to 21.06.2024.	Form CT-11 issued for manufacturing for examination, test and analysis purpose.
5.	23.10.2024 to 24.10.2024	Joint inspection for grant of license in form 28D for additional product.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 23.10.2024 to 24.10.2024 for the purpose of grant of additional products manufacturing licence in Form 28D. During inspection certain observations were noted with respect to validation, material management, Quality management system and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
F.	M/s. Biological E Limited., 18/1 and 3, Azamabad, Hyderabad, Telangana, India, 500020.				
1.	14.08.2024 to 16.08.2024	Joint inspection for grant of CPP as per	Team comprising of officers from	The joint inspection of the firm was carried out from	Firm was directed to submit compliance with

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		WHO guidelines.	CDSCO and state.	14.08.2024 to 16.08.2024 for the purpose of grant of CPP as per WHO guidelines. During inspection certain observations were noted with respect to material management, manufacturing process and control, and documentation.	respect to the observations noted during inspection.
2.	11.11.2024	Compliance verification for inspection dated 14.08.2024 to 16.08.2024.	Team comprising of officers from CDSCO and State	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection 11.11.2024.	Grant of CPP was recommended.
G.	M/s. Human Biologicals Institute (A Division of Immunological Limited) Rakshapuram Gachibowli Hyderabad 500019, T.S..				
1.	06.06.2024 & 07.06.2024	Joint inspection for grant of CPP as per WHO guidelines.	Team comprising of officers from CDSCO and state.	The joint inspection of the firm was carried out from 06.06.2024 & 07.06.2024 for the purpose of grant of CPP as per WHO guidelines. During	Firm was directed to submit compliance with respect to the observations noted during inspection.

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				inspection certain minor observations were noted with respect to material management, manufacturing process and control, and documentation.	
2.	25.07.2024	Compliance verification for inspection dated 06.06.2024 & 07.06.2024	Team comprising of officers from CDSCO and State	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection 25.07.2024	Grant of CPP was recommended.
H.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Sy.No.281-284 & 321, Biotech Park, Phase-III, Karkapatla (V), Markook (M), Siddipet(D), Telangana.				
1.	17.06.2024 to 19.06.2024	Joint inspection for grant of CPP as per WHO guidelines.	Team comprising of officers from CDSCO and state.	The joint inspection of the firm was carried out from 17.06.2024 to 19.06.2024 for the purpose of grant of CPP as per WHO guidelines. During inspection certain minor observations were noted with respect to quality risk assessment, material management,	Firm was directed to submit compliance with respect to the observations noted during inspection.

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				manufacturing process and control and documentation.	
2.	30.08.2024	Compliance verification for inspection dated 17.06.2024 to 19.06.2024 inspection for grant of CPP as per WHO guidelines.	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection on 30.08.2024	Grant of CPP was recommended.
I.	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.	20.03.2024 to 21.03.2024	Compliance verification for inspection dated 13.10.2023 to 14.10.2023 for routine inspection under CIP 2023.	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection from 20.03.2024 to 21.03.2024.	Firm was directed to submit CAPA plan with respect to the remaining observations.
2.	18.04.2024	Compliance verification for inspection dated 27.12.2023 to	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection on 18.04.2024.	Firm was directed to submit CAPA plan with respect to the remaining observations.

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S. No.	Date of Inspection	Purpose of inspection	Team of inspector/ Expert	Remarks/ Conclusions	Regulatory actions (certification and/or enforcement)
		29.12.2023 for grant of CPP as per WHO guidelines.			
3.	27.05.2024 to 29.05.2024	Joint inspection for grant of license in form 28D for additional product.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 27.05.2024 to 29.05.2024 for the purpose of grant of additional products manufacturing licence in Form 28D. During inspection certain minor observations were noted with respect to validation, material management, Quality management system and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
4.	11.06.2023 to 12.06.2023	Compliance verification for inspection dated 13.10.2023 to 14.10.2023 for routine inspection under CIP 2023	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection from 11.06.2023 to 12.06.2023.	Firm was directed to submit CAPA plan with respect to the remaining observations.

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5.	13.06.2024	Compliance verification for inspection dated 27.12.2023 to 29.12.2023 for grant of CPP as per WHO guidelines.	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection on 13.06.2024.	Firm was directed to submit CAPA plan with respect to the remaining observations.
6.	19.08.2024 to 21.08.2024	Joint inspection for grant of license in form 28D for additional product.	Team comprising of officers from CDSCO, State and C DL Kasauli.	The joint inspection of the firm was carried out from 19.08.2024 to 21.08.2024 for the purpose of grant of additional products manufacturing licence in Form 28D. During inspection certain observations were noted with respect to facility, validation, Quality Control, manufacturing and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
7.	28.10.2024	Compliance verification for inspection dated 19.08.2024 to	Team comprising of officers from CDSCO and State	The compliance of the aforesaid observations were verified through joint inspection on 28.10.2024 in which most of the	Licence to manufacture the applied vaccine under Form 28D granted.

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		21.08.2024.		observations were found complied.	
8.	08.10.2024 to 09.10.2024	Joint inspection for NOC to manufacture for Export Purpose.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 08.10.2024 to 09.10.2024 for the purpose of NOC to manufacture for Export Purpose. During inspection certain observations were noted with respect to storage, validation, quality control and manufacture etc.	Firm was directed to submit compliance with respect to the observations noted during inspection.
9.	27.12.2024 to 28.12.2024	Compliance verification for inspection dated 08.10.2024 to 09.10.2024.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The compliance of the aforesaid observations were verified through joint inspection on 27.12.2024 to 28.12.2024.	Firm was directed to submit CAPA plan with respect to the remaining observations.
10.	06.11.2024	For cause inspection	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint investigation of the firm was carried out on 06.11.2024 for the purpose of investigation for actual facts for voluntary recall. During inspection certain observations were noted	Firm was directed to submit compliance with respect to the observations noted during investigation.

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S. No.	Date of Inspection	Purpose of inspection	Team of inspector/ Expert	Remarks/ Conclusions	Regulatory actions (certification and/or enforcement)
				with respect to quality management system, SOP, Storage Condition and documentation.	
J.	M/s Zydus Lifesciences Limited (formerly known as Cadila Healthcare Limited), Survey No. 417, 419 & 420, Sarkhej -Bavla N. H. No. 8A, Village: Moraiya, Tal. Sanand, Dist. Ahmedabad - 382 210, Gujarat				
1.	26.02.2024	Joint inspection for Grant of permission in Form CT 11 for manufacture, examination, test and analysis.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out 26.02.2024 for the purpose of for grant of permission in Form CT 11 for manufacture, examination, test and analysis. During inspection observation was noted with respect to validation, personnel and training and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
2.	16.04.2024	Compliance verification for inspection dated	Team comprising of officers from CDSCO and State.	The compliance of the observations submitted by the firm as CAPA were verified through joint	Form CT-11 issued for manufacturing for examination, test and

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		26.02.2024		inspection on 16.04.2024.	analysis purpose
K.	M/s. Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka , Dist: Ahmedabad -382225, Gujarat				
1.	16.02.2024	Joint inspection for Grant of permission in Form CT 11 for manufacture, examination, test and analysis.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out 16.02.2024 for the purpose of for grant of permission in Form CT 11 for manufacture, examination, test and analysis. During inspection observation was noted with respect to validation, facility and equipment, and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
2.	24.09.2024	Compliance verification for inspection dated 16.02.2024.	Team comprising of officers from CDSCO and State	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection on 24.09.2024.	Form CT-11 issued for manufacturing for clinical trial purpose.
L.	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.				

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S. No.	Date of Inspection	Purpose of inspection	Team of inspector/ Expert	Remarks/ Conclusions	Regulatory actions (certification and/or enforcement)
1.	12.11.2024	Joint inspection for Grant of permission in Form CT 11 for manufacture, examination, test and analysis.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out on 12.11.2024 for the purpose of for grant of permission in Form CT 11 for manufacture, examination, test and analysis. During inspection observation was noted with respect to manufacturing and process, quality management system and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
2.	26.12.2024 to 28.12.2024	Joint inspection for Grant of permission in Form CT 11 for manufacture, examination, test and analysis.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 26.12.2024 to 28.12.2024 for the purpose of for grant of permission in Form CT 11 for manufacture, examination, test and analysis. During inspection observation was noted with respect to facility and equipment, manufacturing and process and	Firm was directed to submit compliance with respect to the observations noted during inspection.

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				documentation.	
M.	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.	15.03.2024	Compliance verification for inspection dated 22.11.2023	Team comprising of officers from CDSCO and State.	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection on 15.03.2024.	Form CT-11 issued for manufacturing for examination, test and analysis purpose
2.	22.04.2024	Joint inspection for Grant of permission in Form CT 11 for manufacture, examination, test and analysis.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 22.04.2024 for the purpose of for grant of permission in Form CT 11 for manufacture, examination, test and analysis. During inspection observation was noted with respect to facility, quality management system and documentation.	Firm was directed to submit compliance with respect to the observations noted during inspection.
3.	12.08.2024	Compliance verification for inspection dated	Team comprising of officers from CDSCO and State.	The compliance of the observations submitted by the firm as CAPA were	Form CT-11 issued for manufacturing for examination, test and

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		22.04.2024		verified through joint inspection on 12.08.2024.	analysis purpose
N.	M/s. Bio-Med Pvt, C-96, Site No.1, Bulandshahr, Road Indl. Area, Ghaziabad				
1.	06.05.2024 to 07.05.2024	Compliance verification for inspection dated 26.12.2023 to 28.12.2023 as routine inspection under CIP 2023.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The compliance of the aforesaid observations were verified through another joint inspection team from 06.05.2024 to 07.05.2024, in which most of the observations were found complied.	1. Firm has complied most of the deficiencies of routine inspection as per Central Inspection Plan 2023. 2. Firm was directed to submit CAPA plan with respect to the remaining observations.
O.	M/s. Bio Vaccines (India) Pvt.Ltd., 46- A, Sanwar Road, Industrial Area, Indore (M.P.) 452015.				
1.	18.03.2024	Compliance verification for inspection dated 01.03.2023 to 03.03.2023 and 28.06.2023 for routine inspection under CIP	Team comprising of officers from CDSCO and State	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection on 18.03.2024.	The compliance of the observations submitted by the firm as CAPA were considered as acceptable.

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		2023			
P.	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Kozhipannai, Pudumund Post, Udthagamandalam 643007, Tamilnadu.				
1.	04.01.2024	For cause inspection	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint investigation of the firm was carried out on 04.01.2024 for the purpose of investigation for AEFI reported on 15.12.2023.	Firm was directed to submit detailed investigation report to CDSCO. The compliance of the observations submitted by the firm as detailed investigation report were verified through desktop review on 08.02.2024 and was considered as acceptable.
2.	06.08.2024 to 08.08.2024	Routine inspection as per Central Inspection Plan-2024.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 06.08.2024 to 08.08.2024 for Routine inspection as per Central Inspection Plan-2024. During inspection observation was noted with	Firm was directed to submit compliance with respect to the observations noted during inspection.

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				respect to validation, facility and equipment, quality management system and documentation.	
Q.	Ms. Green Signal Bio Pharma Ltd., No. 49. Pappankuppam Village, Gummidipoondi, Chennai-601201.				
1.	09.08.2024	Compliance verification for inspection dated 19.09.2022 to 21.09.2022 for post approval change.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The compliance of the observations submitted by the firm as CAPA were verified through joint inspection on 09.08.2024.	PAC NOC issued for the proposed change.
2.	04.06.2024 to 06.06.2024	Routine inspection as per Central Inspection Plan-2024 and additional manufacturing line.	Team comprising of officers from CDSCO, State and CDL Kasauli.	The joint inspection of the firm was carried out from 04.06.2024 to 06.06.2024 for Routine inspection as per Central Inspection Plan-2024 and additional manufacturing line. During inspection observation was noted with respect to validation, facility and equipment, and documentation.	1. Firm was directed to submit compliance with respect to the observations noted during inspection. 2. The compliance of the observations submitted by the firm as CAPA were verified through desktop review on.08.08.2024 3. Firm was directed to submit CAPA plan with respect to the remaining

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					observations of Routine inspection as per Central Inspection Plan-2024. 4. PAC NOC issued for the proposed change.

***Details are available in inspection report along with applicable regulatory action as internal record.**