



(Refer SOP No. QA-INS-010)

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

Draft Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2016

Sl. No.	Name and address of the manufacturing site	Vaccines manufactured (category wise list)	Dt. 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
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A	NORTH ZONE							
1	M/s Biomed Pvt. Ltd, C-96, Site -I, Bulandshahar Road, Ind. Area, Ghaziabad.	Oral Polio Vaccine IP, Vi Polysaccharide Typhoid Vaccine (Bio Typh™), Vi Polysaccharide Typhoid Vaccine (Shan™) Meningococcal Polysaccharide Vaccine, Haemophilus Type-B Conjugate Vaccine 000 Veterinary Vaccines.	12-16 Oct.2015 by CDSCO & State Inspector	Follow-up inspection for compliance verification of the previous inspection.	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	<p>1st Quarter Follow up inspection</p> <p>3rd Quarter Routine inspection</p> <p>4th Quarter Follow up inspection (if any)</p>
2	M/s Pan Era Biotec Pvt. Ltd, Ambala Chandigarh Highway, Lalru, Punjab.	Hepatitis B Vaccine (r DNA) IP (Bulk), Hepatitis B Vaccine (r DNA) BP (Bulk), Hepatitis B Vaccine (r DNA) Bulk drug substance & Haemophilus Type - b Conjugate (PRP - TT) BP (Bulk). Bulk purified	14-15 December 2015 by CDSCO & State Inspector.	To undertake the manufacturing of Pneumococcal Conjugate Bulk Vaccine from VB-IV to VB-III	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	<p>1st Quarter Routine inspection along with follow up of previous inspection.</p> <p>3rd Quarter Follow up inspection (if any)</p>



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		Diphtheria Toxoid, Bulk purified Tetanus Toxoid Pooled Bulk of Whole Cell Pertussis.						
3.	M/s Panacea Biotec Limited, Malpur, Baddi, Tehsil- Nalagarh, Distt. Solan, Himachal Pradesh.	Recombinant Hepatitis B Vaccine IP/BP, DTwP-Hib(Easyfour) , DTwP-Hib-Hepatitis B (Easy five), DTwP-Hib-TT (Easyfive), DT wP-Hepatitis B (Ecovac-4) , Hep B (Enivac HB), Hib (Novohib), Salk based IPV Vaccine (Polprotec) , Haemophilus type b conjugate vaccine BP & DTwP	21-22 Dec. 2015 by CDSCO & State Inspector and expert from CDL, Kasauli	For grant of form 29 and compliance verification of previous inspection.	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	1st Quarter Routine Inspection along with follow up of previous inspection. 3rd Quarter Follow up inspection (if any)



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5	Bharat Immunologicals & Biologicals Corporation Limited (BIBCOL), Village Chola, Dist. Bulandshahar, U. P.	Oral Polio Vaccine IP Trivalent and Bivalent (Type-1 , Type-2 & Type 3)	14-16 Dec.2015 by CDSCO & State Inspector	Routine inspection	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	2st Quarter Follow up inspection 4th Quarter Routine inspection
6	M/s Central Research Institute Kasauli, Distt. Solan (HP)	Diphtheria, Tetanus & Pertusis Vaccine (Adsorbed), Concentrated Diphtheria, Tetanus Pertusis Vaccine (Adsorbed), Tetanus Vaccine (Adsorbed), Diphtheria & Tetanus Vaccine.	09 Dec. 2015 By central, state Drugs inspector and expert from CDL Kasauli	Follow up inspection	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection	Not reported	1st Quarter Follow up inspection 2nd Quarter Routine inspection 4th Quarter Follow up inspection (if any)



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B	SOUTH ZONE							
1	M/s. Green Signal Biopharma, Pvt. Ltd., No. 49, Pappankuppam Village, Gummidipoondi, Chennai 601 201	Bacterial BCG Vaccine (Freeze-Dried) IP / BP / USP / EP	17 & 18 August 2015 By central, state Drugs inspector	Follow up Inspection	As per report	Yes, Compliance met	Not reported	2 nd Quarter Routine inspection 4 th Quarter Follow up inspection (if any)
2	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Kozhipannai, Pudumund Post, Udhamandalam – 643 007 Tamil Nadu	Viral 1. Rabies Vaccine, Human IP, BP 2. Purified Rabies Bulk Antigen	02nd to 04th March 2015 By central and state Drugs inspector	Revalidation of COPP	As per report	Observations communicated to the firm for compliance. To be verified in follow up inspection. Planned on 29-31 Dec 2015	Not reported	2 nd Quarter Follow up inspection 4 th Quarter Routine inspection



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C	WEST ZONE							
1	M/s. Serum Institute of India Ltd, 212/2 Hadapsar, Pune-411028	TT, DT, DPT, Rabies, Hib, Meningococcal A Conjugate vaccine, Influenza vaccine, BCG, Measles, Rubella, MMR, flu vaccine for TT,DTP HiB, DTP HiBHep.B, Rabies vaccine,H1N1	13-21 May 2015 by team WHO PQ Team and CDSCO and State inspectors (aa observer)	For WHO Prequalification as an observer	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	1st Quarter Follow-up inspection 2nd Quarter Routine inspection 3rd Quarter Follow-up inspection 4th Quarter Routine inspection
2	M/s. Haffkine Biopharmaceutical Corporation Ltd. (HBPCL), Parel, Mumbai	OPV	05-08-2015 by team of CDSCO and State inspectors	Investigation- Suspected contamination of hair like material in unopened bOPV vial	As per report	Yes and investigation completed and reported.	Not reported	2nd Quarter Routine inspection 4th Quarter Follow up inspection (if any)
3	M/s Glaxo Smith Kline Asia Pvt. Ltd. Nasik	Labeling and packaging of Inactivated Hepatitis A, Typhoid Polysaccharide Vaccine, Rotavirus, DTP, DTP+ Hepatitis B,	07/12/2015 by team of CDSCO and State inspectors	Additional product approval sterile water for injection (diluent for Vatrrix and Priorix vaccine) in ampoule & FPS packing and labelling and packing for Priorix Tetra vaccine (Measles, Mumps,	As per report	Observations communicated to the firm for compliance . To be verified in	Not reported	2nd Quarter Follow up inspection 4th Quarter Routine inspection



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		Varicella Vaccine		Rubella & Varicella vaccine)		follow up inspection.		
D	HYDERABAD							
1	Bharat Biotech International Ltd. Genome Valley, Turkapally Shameerpet (Mandal) Hyderabad- 500078.	Hepatitis B vaccine, VI Polysaccharide Typhoid vaccine, Hib, DTP+Hib+Hep, Rabies vaccine	18-11-2015 DI, CDSCO, Hyd Expert, CDL, Kasauli and DI, DCA, Hyd, T.S	For Post Approval Changes	As per report	Yes, post approval granted	Yes, Investigated and reported with response to product complaints (Hepatitis B Vaccine 5 ml B. No. 51-AD-13027 and 51-AD- 13036)	1st Quarter Routine Inspection 3rd Quarter Follow-up Inspection (if any))
2	Biological E. Limited D-4-34 Gaganpahad Rajendra Nagar Mandal, R.R., Dist., A.P.	Dedicated bulk antigen facility of TT	21-11-2015 DI, CDSCO, Hyd, Expert, CDL, Kasauli and DI, DCA, Hyd	Follow up Inspection	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	2nd Quarter Routine Inspection along with follow up of previous inspection. 3rd Quarter Follow-up Inspection (if any)



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3	M/s Human Biologicals Institute (A Division of Indian Immunological Limited) Rakshapuram, Gachibowli, Hyderabad-500019.	Hepatitis B vaccine, Tetanus Toxoid vaccine (Adsorbed), DTP vaccine	20.07.2015 & 21.07.2015 DI, CDSKO (HQ), DI, CDSKO, Hyd Expert, CDL, Kasauli and DI, DCA, Hyd, T.S	For Annual Audit Inspection & For Post Approval Changes	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	1st Quarter Routine inspection along with follow up of previous inspection. 3rd Quarter Follow-up Inspection (if any)
4	M/s. Biological E. Limited 18/1 & 3, Azamabad, Hyderabad, AP	DTP bulk, JE Vaccine bulk, TT, bulk	21-11-2015 DI, CDSKO, Hyd, Expert, CDL, Kasauli and DI, DCA, Hyd	Follow up Inspection	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection.	Not reported	2nd Quarter Routine Inspection along with follow up of previous inspection. 3rd Quarter Follow-up Inspection (if any)
5	M/s. Dano Vaccines & Biological Pvt. Limited , 575, Sivareddyguda, Ghatkesar Mandal, R.R. Dist. –	Dedicated bulk antigen facility of TT	16-11-2015 & 17-11-2015 DI, CDSKO, Hyd, Expert, CDL, Kasauli and DI, DCA,	For Annual Audit Inspection	As per report	Observations communicated to the firm for compliance . To be	Not reported	2nd Quarter Routine inspection along with follow up of previous inspection. 4th Quarter



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	501302		Hyd			verified in follow up inspection.		Follow-up Inspection (if any)
6	M/s. Biological E. Limited, Plot no. 1, SP Biotechnology Park Phase II, Kolthru village, Shamarpeet, Madal, Ranga Reddy, Dist., A.P.	DTPw (Whole cell), Diphtheria, Pertusis Hepatitis B vaccine bulk, JE Vaccine, TT, Hepatitis B, DTP+ Hep+Hib	20-11-2015 DI, CDSO, Hyd, Expert, CDL, Kasauli and DI, DCA, Hyd	Follow up Inspection	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection	Not reported	2nd Quarter Routine inspection along with follow up of previous inspection. 4th Quarter Follow-up Inspection (if any)
7	M/s. Shantha Biotechnics Ltd. Survey No. 274, Arthvelli Village, MedchalMandal , Ranga Reddy District, Andhra Pradesh- 501401.	Hepatitis B vaccine, DTP, DTP+Hepatitis B, DTP+ Hepatitis +Hib, TT, Hib, DTP+Hib, Oral Cholera Vaccine, Hepatitis B vaccine bulk, DTP bulk, TT, TT bulk, DTP+ Hep+Hib bulk	16-11-2015 & 17-11-2015 DI, CDSO, Hyd, Expert, CDL, Kasauli and DI, DCA, Hyd	For Annual Audit Inspection	As per report	Observations communicated to the firm for compliance. To be verified in follow up inspection	Not reported	3rd Quarter Routine inspection along with follow up of previous inspection. 4th Quarter Follow-up Inspection (if any)



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E	AHMEDABAD							
1	M/s Cadila Healthcare Limited, Sarkhej- Bavla, NH-8A, Village Moraiya, Dist. Ahmedabad	Rabies Vaccine	WHO PQ Inspection from 26-30 October, 2015	The firm applied for WHO PQ for Rabies vaccine by Chick Embryo Method. As earlier firm had WHO PQ status for Duck embryo method.	Major Non Conformance s reported by the WHO team	No, the firm voluntarily suspended production of rabies vaccine and issued recall notice	Not reported	<p>2nd Quarter Routine inspection along with follow up of previous inspection.</p> <p>4th Quarter Follow-up Inspection (if any)</p>
2	M/s Cadila Healthcare Ltd. Village Changodhar, Tal Sanand, Dist Ahmedabad 382 213	Inactivated Influenza Vaccine (Whole Virion) (Pandemic Influenza (H1N1) 2009 Monovalent Vaccine) (Embryonated hen eggs derived)	07.07.2015 by official of CDSCO, Ahmedabad, State FDCA Gujarat and Subject expert from CDL, Kasauli	Grant of Fresh License	As per report	Yes, Form – 28D granted	Not reported	<p>2nd Quarter Routine inspection</p> <p>4th Quarter Follow-up Inspection (if any)</p>
3	M/s Chiron Behring Vaccine Ltd., Plot No. 3502, GIDC Estate, P.O. 136, Ankleshwar, Gujarat	Rabies Vaccine	03&04.11.2015 by CDSCO, Ahmedabad, State FDCA, Gujarat and Subject expert from CDL, Kasauli	Routine inspection	As per report	Yes, compliance met	Not reported	<p>1st Quarter Routine Inspection along with follow up of previous inspection.</p> <p>4th Quarter Follow-up Inspection (if any)</p>



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4	M/s Cadila Pharmaceuticals Limited, 1389,Trasad Road, Dholka-Ahmedabad, Gujarat	Inactivated Influenza Vaccine (H1N1)	27.04.2015 by official of CDSCO Ahmedabad and FDCA Gujarat	Compliance verification for Grant of Fresh License joint inspection dated 25 and 26.03.2015 by official of CDSCO (HQ), CDSCO Ahmedabad, State FDCA, Gujarat and Subject expert from CDL, Kasauli	As per report	Observations communicated to the firm for compliance . To be verified in follow up inspection	Not reported	2nd Quarter Routine inspection

Note: 1. Additionally, Inspections for selected prequalified vaccine facilities shall be planned as and when Inspections are planned by WHO for prequalification and Central Inspection Plan shall be updated accordingly.