



(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

Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2015

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 and Veterinary Vaccines.	29 & 30 Sep. 2014 by CDSCO & State Inspector	Routine inspection	As per report	No	Nil	<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 Diphtheria Toxoid, Bulk purified Tetanus	08 & 09 Dec. 2014 by CDSCO & State Inspector and expert from CDL Kasauli	Follow up inspection	As per report	No	Nil	<p>1st Quarter Routine inspection</p> <p>3rd Quarter Follow up inspection (if any)</p>



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		Toxoid Pooled Bulk of Whole Cell Pertussis.						
3	M/s Panacea Biotec Ltd, Vaccine Division, A-241, Okhala Ind. Area , Phase – I, New Delhi – 20	Poliomyelitis Vaccine, Live, (Oral), Trivalent IP Monovalent Oral Polio Type 1 Vaccine Monovalent Oral Polio Type 3 Vaccine, Bivalent Poliomyelitis Vaccine Live, (Oral) Injectable vaccine I.e. Easy four (DTwP+CRM Hib), Easyfive Ecovac 4 (DTwP-Hep B), (DTwP+CRM Hib+ Hepatitis B), Enivac HB [Hepatitis B Vaccine (rDNA) IP, HIB.	10 & 11 Dec. 2014 by CDSCO & State Inspector and expert from CDL Kasauli	Follow up inspection	Nil	No	Nil	<p>1st Quarter Follow up inspection</p> <p>3rd Quarter Routine inspection</p> <p>4th Quarter Follow up inspection (if any)</p>



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4	M/s Panacea Biotech 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	10 & 11 Dec. 2014 by CDSCO & State Inspector	Follow up inspection	No	No	Nil	1st Quarter Routine Inspection 3rd Quarter Follow up inspection (if any)
5	Bharat Immunologicals & Biologicals Corporation Limited (BIBCOL) , Village Chola, Dist. Bulandshahar, U. P.	Oral Polio Vaccine IP Trivalent and Monovalent (Type-1 , Type-2 & Type 3)	13 & 14 Nov. 2014 by CDSCO & State Inspector	Routine inspection	As per report	No	Nil	1st Quarter Follow up inspection 3rd Quarter Routine inspection



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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.	01 & 02 Dec. 2014 By central, state Drugs inspector and expert from CDL Kasauli	Follow up inspection	As per report	No	Nil	1st Quarter Follow up inspection 2nd Quarter Routine inspection 4th Quarter Follow up inspection (if any)
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	22 & 23 Dec. 2014 By central, state Drugs inspector	Follow up Inspection	As per report	No	Nil	2nd Quarter Routine inspection 4th Quarter Follow up inspection (if any)



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2	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Kozhipannai, Pudumund Post, Udthagamandalam – 643 007 Tamil Nadu	Viral Rabies Vaccine (Vero Cell) IP, BP, USP,	19 & 20 Dec. 2014 By central, state Drugs inspector	Routine inspection	As per report	No	Nil	1st Quarter Follow up inspection 3rd Quarter Routine inspection
3.	Ranbaxy Laboratories Limited , Survey No.16, Ekarajapura, Siddlaghatta Road, Hoskote, Bangalore-562114	1.Heamphilus Influenze Type B Conjugate Vaccine 2.Vi Capsular Polysaccharide Typhoid vaccine	12 & 13/11/2013 by team of CDSCO and State Inspector and expert from CDL, Kasauli	Compliance verification of previous inspection dated 22 & 23/03/2012	As per report	No	Nil	2nd Quarter Routine inspection 4th Quarter Follow up inspection (if any)



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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	21 to 22 November, 2014 by team of CDSCO and State inspectors	Permission to commence additional vaccine manufacturing facility in SEZ-1C/2 nd floor.	As per report	No	Yes, Investigated and reported	1 st Quarter Follow up inspection 3 rd Quarter Routine inspection
2	M/s. Haffkine Biopharmaceutical Corporation Ltd. (HBPCL), Parel, Mumbai	OPV	04.07.2014 by team of CDSCO and State inspectors	For verification of CAPA submitted to WHO related to assessment of acceptability of OPV.	As per report	No	Nil	2 nd Quarter Routine inspection 4 th 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	20.01.2014 by team of CDSCO and State inspectors	Renewal of Mfg. License in form 28-D	As per report	No	Nil	2 nd Quarter Routine inspection 4 th Quarter Follow up inspection (if any)



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		B, Varicella Vaccine						
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	22 to 24- Sep. 2014 by team of CDSCO and State Inspector	Routine inspection & for Pre-WHO PQ audit for verification of CAPA for "Oral Polio Vaccine"	As per report	No	Nil	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	24-03-2014 by team of CDSCO and State Inspector and expert from CDL, Kasauli	Routine inspection	As per report	No	Nil	2nd Quarter Routine 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	24-12-2014 by team of CDSCO and State Inspector	For Annual Audit Inspection & For product complaints inspection	As per report	NA	Yes, Investigated and reported with response to product complaints (DTP Vaccine IP B.No-TAG05A/14	1st Quarter Routine 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	20 to 22- Dec. 2014 by team of CDSCO and State Inspector	Routine inspection	As per report	No	Nil	2nd Quarter Routine Inspection 3rd Quarter Follow-up Inspection (if any)
5	M/s. Dano Vaccines & Biological Pvt. Limited , 575, Sivareddyguda, Ghatkesar Mandal, R.R. Dist. – 501302	Dedicated bulk antigen facility of TT	20-12-2014 by team of CDSCO and State Inspector and expert from CDL, Kasauli	Routine inspection	As per report	No	Nil	2nd Quarter Routine Inspection 3rd Quarter Follow-up Inspection (if any)



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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), Diptheria, Pertusis Hepatitis B vaccine bulk, JE Vaccine, TT, Hepatitis B, DTP+ Hep+Hib	18 & 19 Dec. 2014 by team of CDSCO and State Inspector and expert from CDL, Kasauli	Routine inspection	As per report	No	Nil	2nd Quarter Routine Inspection 3rd 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	18 & 19 Dec. 2014 by team of CDSCO and State Inspector and expert from CDL, Kasauli	Routine inspection	As per report	No	Nil	3rd Quarter Routine 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, District Ahmedabad.	Inactivated Influenza vaccine (Whole Virion), Rabies vaccine	11 & 12 July 2014 by CDSO & State Inspector and expert from CDL, Kasauli	Routine inspection	As per report	No	Nil	2nd Quarter Follow up inspection 4th Quarter Routine inspection
2	M/s Chiron Behring Vaccine Ltd Plot No 3502, G.I.D.C Estate, P.O. 136, Ankleshwar, Gujarat.	Rabies vaccine	09 & 10 July 2014 by CDSO & State Inspector	Routine inspection	As per report	No	Nil	2nd Quarter Follow up inspection 4th 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.