



(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 2017

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
A NORTH ZONE								
1	M/s Biomed Pvt. Ltd, C-96, Site –I, Bulandshahar Road, Ind. Area, Ghaziabad.	1. Oral Polio Vaccine IP, 2. Vi Polysaccharide Typhoid Vaccine (Bio Typh™) IP, 3. Haemophilus Type-B Conjugate Vaccine (PedaHib) 4. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W 135) QuadriMeningo 5. Meningococcal Polysaccharide Vaccine (Group A&C) Bivalent 6. Vi Conjugate Typhoid Vaccine (Peda Typh), 7. Vi Conjugate Typhoid Vaccine (Bio Typh™), 8. Haemophilus Type-B Conjugate Vaccine (PedaHib) IP 9. Meningococcal	29-30 Sep 2016 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	1 st Quarter Follow up inspection 3 rd Quarter Annual inspection



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		Polysaccharide Vaccine (Group A,C,Y,W 135) IP QuadriMeningo 10. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W 135) Ph. Euro QuadriMeningo 11. Meningococcal Polysaccharide Vaccine (Group A&C) Bimeningo 12. Meningococcal Polysaccharide Vaccine (Group A,C,Y,W 135) QuadriMeningo , Nm Vac-4 ACYW135. 13. Veterinary Vaccines.						
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 &	27& 28 Sept 2016 by CDSCO, State Inspector & expert from CDL, Kasauli	Follow up Inspection of the previous joint inspection.	As per report	Yes, compliance met	Not reported	1 st Quarter Annual inspection



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		Haemophilus Type – b Conjugate (PRP - TT) BP (Bulk). Bulk purified Diphtheria Toxoid (D), Bulk purified Tetanus Toxoid (T) Pooled Bulk of Whole Cell Pertussis (WP).						
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, Pandynflu &	25-26 Nov 2016 by CDSCO & State Inspector and expert from CDL, Kasauli	For grant of additional products and renewal of GMP Certificate	As per report	Observations Communicate to the firm for Compliance. To be verified in follow up inspection.	Not reported	2 nd Quarter Follow up Inspection 4 th Quarter Annual inspection



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		DTwP						
4	Bharat Immunological s & Biologicals Corporation Limited (BIBCOL), Village Chola, Dist. Bulandshahar, U. P.	1. Trivalent Oral Poliomyelitis Vaccine IP 2. Bivalent Oral Poliomyelitis Vaccine –Sabin strain (Type-1 & Type 3)	21-24 Nov 2016 by CDSCO & State Inspector and expert from CDL, Kasauli	Routine inspection along with follow up inspection of the earlier inspection	As per report	Observations Communicated to the firm for Compliance. To be verified in follow up inspection.	Not reported	1 st Quarter Follow up inspection 4th Quarter Annual inspection
5	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 (Adsorbed).	27-28 Dec 2016 By central, state Drugs inspector and expert from CDL Kasauli	Routine inspection and Follow up for the previous inspection	As per report	Observations Communicated to the firm for Compliance. To be verified in follow up inspection.	Not reported	1 st Quarter Follow up inspection 2 nd Quarter Annual inspection



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B	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/EPP	08-10 Dec.2016 By central, state Drugs inspector expert from CDL, Kasauli	Follow up inspection of the earlier inspection along with grant of post approval changes and renewal of GMP certificate	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection.	Not reported	3 rd Quarter Annual inspection along with follow up of the earlier inspection.
2	M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Kozhipannai, Pudumund Post, Udhagamandalam – 643 007 Tamil Nadu	Rabies Vaccine, Human IP, BP, Purified Rabies bulk antigen	05-07 Dec 2016 by CDSCO and State Inspector	Follow up Inspection	As per report	No	Not reported	4 th Quarter Annual inspection along with follow up inspection of the earlier 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	06 Oct 2016 by CDSCO and State inspectors	For utilization of cold room facility	As per report	Yes, compliance met	Not reported	2 nd Quarter Annual inspection
2	M/s. Haffkine Biopharmaceutical Corporation Ltd. (HBPCL), Parel, Mumbai	OPV	17-19 Oct 2016 by team of CDSCO, State inspectors and expert from CDL, Kasuali	WHO observed audit NRA Assessment	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection.	Not reported	2 nd Quarter Follow up inspection 4 th Quarter Annual inspection
3	M/s Glaxo Smith Kline Asia Pvt. Ltd. Nasik-422010	Labeling and packaging of Inactivated Hepatitis A, Typhoid Polysaccharide Vaccine, Rotavirus, DTP, DTP+	16 June 2016 by team of CDSCO and State inspectors	Renewal of mfg. license	As per report	Yes, compliance met	Not reported	2 nd Quarter Annual inspection



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		Hepatitis B,						
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	17-19 August 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	Routine Inspection	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection.	Not reported	1 st Quarter Follow up Inspection 4th Quarter Annual Inspection
2	Biological E. Limited 7-4-34 Gaganpahad Rajendra Nagar Mandal, R.R., Dist., TS.	Dedicated bulk antigen facility of TT	08-09 September 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	Routine Inspection	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection.	Not reported	2 nd Quarter Annual Inspection along with Follow up Inspection



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3	M/s Human Biologicals Institute (A Division of Indian Immunological Limtied) Rakshapuram, Gachibowli, Hyderabad-500019, TS	Hepatitis B vaccine, Tetanus Toxoid vaccine (Adsorbed), DTP vaccine	4-5 March 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	Routine Inspection	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection.	Not reported	1 st Quarter Follow-up Inspection 3rd Quarter Annual Inspection
4.	M/s Human Biologicals Institute Survey No. 281 to 284 and 321, Karakapatla (V), Medak 502281, TS	Inactivated Rabies Vaccine	06-07 September 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	For Annual audit using risk based approach	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection.	Not reported	2 nd Quarter Annual Inspection along with follow up inspection of earlier inspection.
5	M/s. Biological E. Limited 18/1 & 3, Azamabad, Hyderabad, TS	DTP bulk, JE Vaccine bulk, TT, bulk	19-20 Aug 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	Routine Inspection	As per report	Observations Communicated to the firm for compliance. To be verified in	Not reported	2 nd Quarter Follow up Inspection 4 th Quarter Annual Inspection



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						follow up inspection.		
6	M/s. Dano Vaccines & Biological Pvt. Limited, 575, Sivareddyguda, Ghatkesar Mandal, R.R. Dist. – 501302	Dedicated bulk antigen facility of TT	16-11-2015 & 17-11-2015 by CDSCO, State inspectors and expert from CDL, Kasuali	Routine Inspection	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection	Not reported	1 st Quarter Annual inspection along with Follow up Inspection of the earlier inspection.
7	M/s. Biological E. Limited, Plot no. 1, SP Biotechnology Park Phase II, Kolthru village, Shamarpeet, Madal, Ranga Reddy, Dist., TS.	DTPw (Whole cell), Diptheria, Pertusis Hepatitis B vaccine bulk, JE Vaccine, TT, Hepatitis B, DTP+ Hep+Hib	17-18 August 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	Routine Inspection	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection	Not reported	1 st Quarter Follow up inspection 4th Quarter Annual inspection
8	M/s. Shantha Biotechnics Ltd. Survey No. 274, Arthvelli Village,	Hepatitis B vaccine, DTP, DTP+Hepatitis B, DTP+ Hepatitis +Hib, TT, Hib, DTP+Hib, Oral	20 Aug 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	For verification of the status of the GMP compliance and factual status of reported NSQ	As per report	Investigation completed and reported	Not reported	1 st Quarter Annual inspection



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	MedchalMandal, Ranga Reddy District, Andhra Pradesh- 501401.	Cholera Vaccine, Hepatitis B vaccine bulk, DTP bulk, TT, TT bulk, DTP+ Hep+Hib bulk						
9	M/s. Shantha Biotechnics Ltd., Sy. No. 354, Muppireddypally (V), Toopran (M), Medak Dist, T.S.	TT Antigen and TT Carrier	19-10-2015 & 20-10-2015 DI, CDSCO, Hyd, Expert, CDL, Kasauli and AD, DCA, TS & DI, DCA, Hyd, TS.	For Grant Inspection & For Post Approval Changes	NA	NA	Not reported	1st Quarter Routine Inspection 3rd Quarter Follow-up Inspection (if any)
E	AHMEDABAD							
1	M/s Cadila Healthcare Limited, Sarkhej-Bavla, NH-8A, Village Moraiya, Dist. Ahmedabad License No. G/Vac-1 in	Rabies Vaccine	11 & 12 July, 2014 by CDSCO, State inspectors and expert from CDL, Kasauli	Routine inspection as per Central Inspection Plan	As per report	Observations Communicated to the firm for compliance. To be verified in follow up inspection	Not reported	1 st Quarter Annual Inspection along with follow up of the earlier inspection



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	form 28-D dated 10/11/2000							
2	M/s Cadila Healthcare Ltd. Village Changodhar, Tal Sanand, Dist Ahmedabad 382 213 Lic.No. G/28D/Vac/03 Dated 05.08.2015	Inactivated Influenza Vaccine (Monovalent Vaccine, Trivalent Influenza and etravalent (Split Virion) I.P. – Single Dose (Embryonated hen eggs derived)	11-12August, 2016 by CDSCO, State inspectors and expert from CDL, Kasuali	Grant of additional product	As per report	Yes, compliance met	Not reported	2 nd Quarter Annual Inspection
3	M/s Chiron Behring Vaccine Ltd., Plot No. 3502, GIDC Estate, P.O. 136, Ankleshwar, Gujarat License No. in form 28-D/G/LVP-2, dated 20/06/2001	Rabbies Vaccine	04- 05 October, 2016 by CDSCO and State inspectors	Post approval change and follow up inspection	As per Report	Observations Communicated to the firm for compliance. To be verified in follow up inspection	Not reported	2 nd Quarter Annual Inspection along with follow up of the earlier inspection



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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.
2. Further it is pertinent to mention that all biological products inspections for other than investigation/grant/renewal of license, shall be carried out usually once in a year, unless otherwise justified based on risk based analysis of the firms, products and issue requiring inspection as per Directorate Office Memorandum no File No X-11026/143/16-BD dated 20.12.2016.