(Refer SOP No. QA-INS-010)

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Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2018

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^{TM}) IP, 3. Haemophilus Type-B Conjugate Vaccine (PedaHib) 4. Meningococal Polysaccharide Vaccine (Group A,C,Y,W 135) QuadriMeningo 5. Meningococal Polysaccharide Vaccine (Group A&C) Bivalent 6. Vi Conjugate Typhoid Vaccine (Peda Typh), 7. Vi Conjugate Typhoid Vaccine (Bio Typh^{TM}), 8. Haemophilus Type-B Conjugate Vaccine (PedaHib) IP 9. Meningococal Polysaccharide Vaccine (Group A,C,Y,W 135) IP QuadriMeningo 10. Meningococal Polysaccharide Vaccine (Group A,C,Y,W 135) Ph. Euro QuadriMeningo 11. Meningococal Polysaccharide Vaccine (Group A&C) Bimeningo 12. Meningococal Polysaccharide	05-06/October/2017 by CDSCO & State Inspector & CDL Kasauli	Routine Inspection as per Central Inspection Plan 2017	Yes, as per report	No	Not reported	1st Quarter Follow up inspection 3rd Quarter Annual inspection

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		Vaccine (Group A,C,Y,W 135) QuadriMeningo , Nm Vac-4 ACYW135. 13. Veterinary Vaccines.						
2	**Bharat Immunologicals & 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)	14-15/November/ 2017 by CDSCO & State Inspector	Follow up inspection of the previous inspection dated 10.07.2017-11.07.2017	Nil, as per report	Yes, except one observation	Not reported	2nd Quarter Annual inspection along with compliance verification of pending non-compliance 4th Quarter Follow up inspection
3	**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 (D), Bulk purified Tetanus Toxoid (T), Pooled Bulk of Whole Cell Pertussis (WP).	20- 21/ April 2017 by CDSCO, State Inspector & expert from CDL, Kasauli	Routine Inspection as per Central Inspection Plan 2017	Yes, as per report	Yes, compliance met	Not reported	2nd Quarter Follow up inspection 4th Quarter Annual inspection

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4.	**M/s Panacea Biotec Limited, Malpur, Baddi, Tehsil-Nalagarh, Distt. Solan, Himachal Pradesh.**	1. Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r-DNA) and Haemophilus Influenza Type-b conjugate vaccine (adsorbed) IP (easyfive-TT) 2. Inactivated H1N1 split Virion Influenza vaccine (adjuvanted) (Pandyflu) 3. Diphtheria, Tetanus and Pertussis vaccine (adsorbed) IP 4. Bivalent Poliomyelitis vaccine Type-1 & Type-3, Live (oral) (P.T. Biofarma Indonesia) 5. Bivalent Poliomyelitis vaccine Type-1 & Type-3, Live (oral) (Sanofi Pasteur France) 6. Haemophilus type B conjugate vaccine IP (NovoHib) 7. Haemophilus type B conjugate vaccine BP (NovoHib) 8. EasySix^{TM} purified Diphtheria Toxoid, Purified Tetanus Toxoid, whole cell Pertussis, Recombinant Hepatitis B, Haemophilus Influenzae Type-B conjugate and inactivated Poliomyelitis Trivalent vaccine (adsorbed)	07-08/ December/ 2017 by CDSCO & State Inspector and expert from CDL, Kasauli	Annual Inspection as per Central Inspection Plan 2017	Nil, as per report	Observations communicated to the firm for compliance. and to be verified in follow up inspection.	Not reported	2nd Quarter Follow up inspection 4th Quarter Annual inspection

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		9. Hepatitis B vaccine (rDNA) IP (Enivac HB) 10. Hepatitis B vaccine (rDNA) BP (Enivac HB)						
5	**M/s Central Research Institute Kasauli, Distt. Solan (HP)**	Diphtheria, Tetanus & Pertussis Vaccine (Adsorbed), Concentrated Diphtheria, Tetanus Pertussis Vaccine (Adsorbed), Tetanus Vaccine (Adsorbed), Diphtheria & Tetanus Vaccine (Adsorbed).	28 - 29/December/ 2017 By CDSCO, state Drugs inspector and expert from CDL Kasauli	Annual Inspection as per Central Inspection Plan 2017	Report is under examination	Report is under examination	Report is under examination	2nd Quarter Follow up inspection 4th Quarter Annual inspection
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	31/August/2017 to 02/September/ 2017 By CDSCO, state Drugs inspector and expert from CDL, Kasauli	Annual Inspection as per Central Inspection Plan 2017 and compliance verification of previous inspection dated 08-10/December/2016	Nil, as per report	Observations communicated to the firm for compliance and to be verified in follow up inspection.	Not reported	3rd Quarter Annual inspection along with follow up of the earlier inspection.

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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	19-21/ December/ 2017 by CDSCO and State Inspector	Joint inspection as per Central Inspection Plan 2017 and compliance verification of previous inspection dated 10-12/April/2017	Nil, as per report	Observations communicated to the firm for compliance and to be verified in follow up inspection.	Not reported	3rd Quarter Annual inspection along with follow up inspection of the earlier inspection
3.	**M/s. HLL Biotech Limited (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise), Integrated Vaccines Complex (IVC), Survey No. 192 & 195,**	1. Hepatitis B Vaccine (rDNA) I.P. (For Paediatric Use) (Single Dose Vial – 0.5 ml & Ten Dose Vial – 5 ml), 2. Hepatitis B Vaccine (rDNA) I.P. (For Adult Use) (Single Dose Vial – 1.0 ml & Ten Dose Vial – 10 ml). 3. Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Influenzae Type b Conjugate Vaccine (Adsorbed) I.P. (DTwP-rHepB-Hib)(Single	07/November/ 2017 By CDSCO and state drugs inspectors	Compliance verification of observations of previous joint inspection dated 04- 06/July/2017	Nil, as per report	Yes, compliance met	Not reported	Annual inspection to be planned after grant of license in Form-28D

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	Thirumani Village, Thirukazhukundram (TK), Chengalpattu, Kanchipuram District - 603001, Tamilnadu	Dose Vial – 0.5 ml & Ten Dose Vial – 5 ml)						
4	**M/s. Venky Parenterals, Adavipolam, Yanam-533464, Tamil Nadu, India,**	Tetanus Vaccine (Adsorbed) IP and Adsorbed Tetanus Vaccine BP	09-10/November/ 2017 By CDSCO and state drugs inspectors and expert from CDL, Kasauli	For renewal of manufacturing license	Yes, as per report	Observations communicated to the firm for compliance and to be verified in follow up inspection.	Not reported	3rd 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	31/July/2017 to 04/August/2017 by CDSCO and State inspectors and expert from CDL, Kasauli	Annual routine inspection as per Central Inspection Plan-2017	Yes, as per report	Observations communicated to the firm for compliance and to be verified in follow up inspection	Not reported	2nd Quarter follow up inspection and Annual inspection 4th Quarter follow up (if any) inspection and Annual inspection
2	**M/s. Haffkine Biopharmaceutical Corporation Ltd. (HBPCL), Parel, Mumbai**	OPV	28-29/Dec/2017 by team of CDSCO, State inspectors and expert from CDL, Kasauli	Annual routine inspection as per Central Inspection Plan-2017	Report is under examination	Report is under examination	Report is under examination	1st Quarter Follow up (if any) 3rd Quarter Annual inspection
D	HYDERABAD ZONE							
1	**Bharat Biotech International Ltd. Genome Valley, Turkapally Shameerpet (Mandal)**	Hepatitis B vaccine, VI Polysaccharide Typhoid vaccine, Hib, DTP+Hib+Hep, Rabies vaccine, oral polio vaccines(tOPV), oral rotavirus vaccines	22-23/Nov/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Compliance verification of previous joint annul inspection dated 10-11/July/2017 2. For the grant of post approval NOC for additional new	Yes, as per report	Observations communicated to the firm for compliance and to be verified in follow up	Not reported	1st Quarter Annual inspection 3rd Quarter Follow-up inspection (if any) and Annual

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	Hyderabad-500078.			manufacturing facility at PB4.		inspection		inspection
2	**Biological E. Limited 7-4-34 Gaganpahad Rajendra Nagar Mandal, R.R., Dist., TS.**	Tetanus vaccine(adsorbed)(Bulk), Diptheria antitoxin 1000 IU(Bulk), Diptheria antitoxin 20,000 IU(Bulk), Tetanus antitoxin (Bulk)	05-06/June/2017 by CDSCO and State inspectors and expert from CDL, Kasauli	Annual Routine Inspection as per Central Inspection Plan-2017 and compliance verification of previous inspection dated 08-09/Sept/2016 & 02-04/Jan/2017	Nil, as per report	Observations communica-ted to the firm for compliance and to be verified in follow up inspection.	Not reported	2nd Quarter Annual inspection 4th Quarter Follow-up inspection (if any)
3	**M/s. Biological E. Limited 18/1 & 3,Azamabad, Hyderabad, TS**	Tetanus vaccine (adsorbed), DTP vaccine (adsorbed), DT vaccine (adsorbed), Tetanus antitoxin, Diptheria antitoxin, JE inactivated vaccine	09-10/June/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	Annual Routine Inspection as per Central Inspection Plan-2017	Yes, as per report	Observations communica-ted to the firm for compliance and to be verified in follow up inspection.	Not reported	2nd Quarter Annual inspection 4th Quarter Follow-up inspection (if any) .

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4.	**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	07-08/June/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	Annual Routine Inspection as per Central Inspection Plan-2017	Yes, as per report	Observations communica-ted to the firm for compliance and to be verified in follow up inspection	Not reported	2nd Quarter Annual inspection 4th Quarter Follow-up inspection (if any) and annual inspection
5	**M/s. Dano Vaccines & Biological Pvt. Limited, 575, Sivareddygud, GhatkesarMandal, R.R. Dist. – 501302**	Dedicated bulk antigen facility of TT, bulk purified toxoid IP-NLT 2500 Lf/ml, adsorbed tetanus vaccine BP, bulk purified toxoid B.P-NLT-2500 Lf/ml	06-08/March/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Annual Routine Inspection as per Central Inspection Plan-2017. 2. Grant of license for additional products. 3. Follow up inspection for the previous inspection dated 30/Jan/2017	Yes, as per report	Observations communica-ted to the firm for compliance and to be verified in follow up inspection.	Not reported	1st Quarter Annual inspection 3rd Quarter Follow-up inspection (if any) .
6	**M/s Human Biologicals Institute Survey No. 281 to 284 and 321,**	Inactivated Rabies Vaccine	14-15/July/2017 by CDSCO, State inspectors and expert from	Annual Routine Inspection as per Central Inspection Plan-2017	Yes, as per report	Observations Communica-ted to the firm for compliance and to be	Not reported	3rd Quarter Annual inspection 4th Quarter Follow-up inspection (if any)

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	Karakapatla (V), Medak 502281,TS		CDL, Kasauli			verified in follow up inspection.		.
7	**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 and Inactivated Rabies vaccine	12-13/July/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Annual Inspection as per Central Inspection Plan-2017. 2. For grant of additional product licensed in Form-28D.	Yes, as per report	Observations Communicated to the firm for compliance and to be verified in follow up inspection	Not reported	3rd Quarter Annual inspection 4th Quarter Follow-up inspection (if any)
8	**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	06-08/March/2017 to, by CDSCO, State inspectors and expert from CDL, Kasauli	Annual Inspection as per Central Inspection Plan-2017 and compliance verification of previous inspection dated 16-17/November/2015	Yes, as per report	Observations communica-ted to the firm for compliance and to be verified in follow up inspection	Not reported	1st Quarter Annual inspection 3rd Quarter Follow-up inspection (if any) and annual inspection

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9	**M/s. Shantha Biotechnics Ltd., Sy. No. 354, Muppireddypally (V), Toopran (M), Medak Dist, T.S.**	Cholera Vaccine (Iactivated oral), DTP (whole cell), Hepatitis-B (rDNA) & Hib Conjugate Vaccine (Adsorbed)	08-09/June/2017 DI, CDSCO, state, Expert, CDL, Kasauli and AD, DCA,TS & DI, DCA, Hyd, TS.	Annual Inspection as per Central Inspection Plan-2017 and grant of NOC for post approval changes	Nil, as per report	Observations communicated to the firm for compliance and to be verified in follow up inspection	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 form 28-D dated 10/11/2000**	Rabies Vaccine	08/Nov/2017 by CDSCO, State inspectors	Compliance verification of previous inspection dated 27-28/July/2017.	Yes, as per report	Yes, the firm has submitted compliance report and has been verified	Not reported	4th Quarter Routine Inspection

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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 tetravalent (Split Virion) I.P. – Single Dose (Embryonated hen eggs derived), Typhoid vaccine I.P.	29-30/June/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Annual Routine Inspection as per Central Inspection Plan-2017. 2. To verify the compliance of previous joint inspection dated 11-12/August/2016.	Yes, as per report	Observations communicated to the firm for compliance and to be verified in follow up inspection	Not reported	2nd Quarter Annual Inspection and follow up inspection
3	**M/s Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka-Ahmendabad, Gujarat**	Inactivated Influenza vaccine(H1N1)	21-22/Dec/2017, by CDSCO, State inspectors and expert from CDL, Kasauli	Annual Routine Inspection as per Central Inspection Plan-2017	Report is under examination	Report is under examination	Report is under examination	2nd Quarter Annual Inspection and follow up inspection

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4.	**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**	Rabies Vaccine	27-28/June/2017 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Annual Routine Inspection as per Central Inspection Plan-2017. 2. For detail investigation on positive results of endotoxins in four final batches of Rabipur lot specific for China.	Yes, as per report.	No, Firm has not submitted compliance report yet.	Yes, 04 batches failed in BET supplied to China.	1st Quarter follow up.

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 product 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.**