(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 2019

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 olysaccharide Typhoid Vaccine (Bio TyphTM) 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 TyphTM), 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 Vaccine (Group A, C, Y, W 135) QuadriMeningo, Nm Vac-4 ACYW135. 13. Veterinary Vaccines.	03.10.2018 to 06.10.2018 & 08.10.2018 ADC(I) and DIs of CDSCO, , and DI, Uttar Pradesh	To find out the root cause for the NSQ Reported	As per report	Observations communicated to the firm for compliance.	NSQ Reported	**1st Quarter** Annual Inspection **2nd Quarter** Follow-up Inspection (if any) **3rd Quarter** Annual Inspection **4th Quarter** Follow-up Inspection (if any)
2	**Bharat Immunological s & Biologicals Corporation Limited (BIBCOL),**	1.Oral Polio Vaccine IP	04. 10.2018 DIs of CDSCO, and DI, Uttar Pradesh	Compliance verification	As per report	Observations communicated to the firm for compliance.	Not reported	**2nd Quarter** Annual Inspection **4th Quarter** Follow-up Inspection

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	Village Chola, Dist. Bulandshahar, U. P.							(if any**)**
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).	06-07/ December/ 2018 by CDSCO & State Inspector and expert from CDL, Kasauli	Annual routine inspection as per Central Inspection Plan-2018	Yes, as per report	Report under signing	Not reported	**1st Quarter** Follow up inspection **3rd Quarter** Annual inspection
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)	26- 27/ Dec 2018 by CDSCO, State Inspector & expert from CDL, Kasauli	Annual Inspection as per Central Inspection Plan 2018 Grant of NOC to obtain manufacturing license in Form-29	As per report	Compliance report awaited	Not reported	**1st Quarter** Follow up inspection **2nd Quarter** Annual inspection

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		8. EasySix™ purified Diphtheria Toxoid, Purified Tetanus Toxoid, whole cell Pertussis, Recombinant Hepatitis B, Haemophilus Influenzae Type-B conjugate and inactivated Poliomyelitis Trivalent vaccine (adsorbed) 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).	01 -02/June/ 2018 By CDSCO, state Drugs inspector and expert from CDL Kasauli	2nd quarter follow up inspection as per Central Inspection Plan 2018	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
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	24-26 /September/ 2018 By central, state Drugs Inspector along with expert from CDL, Kasauli	1.Central Inspection Plan, 2018 2.Compliance verification of previous inspection from 12.07.2018-13.07.2018 3.Verification of post approval changes submitted under annual notification 4. Compliance verification of previous inspection from	Yes , as per report	Observations Communicated to the firm for Compliance. To be verified in follow up Inspection.	Not reported	**1st quarter** follow-up And **2nd quarter** Annual inspection

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Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2019

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
				31.08.2017 to 02.09.2017				
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	26-28/ December/ 2018, By Central, State Drugs Inspector along with expert from CDL, Kasauli	1.Central Inspection Plan, 2017, 2.Renewal of WHO GMP, 3.Post approval changes, 4. Approval of notifiable changes 5.Compliance verification of previous inspection from 19.12.2017 to 21.12.2017	Inspection is conducted on last week of December - 2018.	Inspection is conducted on last week of December - 2018 and the report is under preparation.	Not reported	**4th 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, Thirumani Village, Thirukazhukundram (TK),**	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 Dose Vial – 0.5 ml & Ten Dose Vial – 5 ml)	07.11.2017 By central and state drugs inspectors	Compliance verification of observations of previous joint inspection conducted from 04-07-2017 to 06-07-2017, for the grant of Licence in Form - 28D.	NIL	Yes, Compliance met	Not reported	**1st Quarter** Annual Inspection

Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2019

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
	Chengalpattu, Kanchipuram District - 603001, Tamilnadu							
4	**M/s.Venky Parenterals, Adavipolam, Yanam–533464, Puducherry UT, India.**	1. Tetanus Vaccine (Adsorbed) IP 2. Adsorbed Tetanus Vaccine BP)	15-16 October/2018. By Central, State Drugs Inspectors along with expert from CDL, Kasauli	Compliance verification for the previous inspection held on 9.11.2017 to 10.11.2017	Yes, as per report	Observations recently Communicated to the firm.	Not reported	Annual Inspection may be planned after Renewal of Manufacturing License
5.	**M/s. BCG Vaccine Lab, No. 110, 110A, 33 Feet Road, Mount Road, Guindy, Chennai, Pin-600 032, Tamilnadu**	Freeze Dried BCG Vaccine I.P doses.	27-29/September/ 2018 By Central, State Drugs Inspector along with expert from CDL, Kasauli	Joint inspection for grant of manufacturing license in Form 28 D for the applied product "Freeze Dried BCG Vaccine IP".	As per report	Observations Communicated to the firm for Compliance. To be verified in follow up inspection	Not reported	Annual Inspection may be planned after grant of Form 28 D

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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
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	18/Dec/2018 to 19/Dec/2018 by CDSCO and State inspectors and expert from CDL, Kasauli	Annual routine inspection as per Central Inspection Plan-2018	Yes, as per report	As per report	Reported	**2nd Quarter** Annual inspection **4th Quarter** Annual inspection
2	**M/s. Haffkine Biopharmaceutical Corporation Ltd. (HBPCL), Parel, Mumbai**	OPV	21-22/Dec/2018 by team of CDSCO, State inspectors and expert from CDL, Kasauli	Annual routine inspection as per Central Inspection Plan-2017	As per report	As per report	Not reported	**3rd Quarter** Annual inspection
D	**HYDERABAD ZONE**							
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, oral polio vaccines(tOPV), oral rotavirus vaccines	31/Oct/18-01/Nov/2018 by CDSCO, State inspectors and expert from CDL, Kasauli	1. To verify tenet of GMP as per PAC 2. For the grant of Form 29 NOC 3. For the verification of PAC along with suitability of PA1 facility for the manufacture & filling of JE vaccines.	As per report	Observations communicated to the firm for compliance and to be verified in follow up inspection	Not reported	**1st Quarter** Follow-up inspection **3rd Quarter** Annual inspection

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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)	04-05/June/2018 by CDSCO and State inspectors and expert from CDL, Kasauli	Annual Routine Inspection as per Central Inspection Plan-2018 and compliance verification of previous inspection dated 05-06/June/2017 & 20/Nov/2017	As per report one major observation	Observations communicated 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	08-09/June/2018 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Annual Routine Inspection as per Central Inspection Plan-2018 2. For the verification of CAPA for the inspection carried out on 09-10/June/2017 3. For the grant of license for the additional product (Japanese Encephalitis Vaccine Inactivated (Absorbed Human) IP) in Form 28D	--	Observations communicated 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	29-30/Oct/2018 by CDSCO, State inspectors and expert from CDL, Kasauli	For the grant of Form 29 NOC for the antisera products	---	Observations communicated 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)
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	14-15/June/2018 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Annual Routine Inspection as per Central Inspection Plan-2018. 2. Follow up inspection for the previous inspection dated 16-17/Jan/2018	As per report	Observations communicated 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) & Annual Inspection .
6	**M/s Human Biologicals Institute Survey No. 281 to 284 and 321, Karakapatla (V), Medak 502281,TS**	Inactivated Rabies Vaccine	04-10/Oct/2018 by CDSCO, State inspectors and expert from CDL, Kasauli	For verification of documents to related to manufacturing of Rabies Bulk vaccine with respect to complaint received from CDSCO(HQ)	----	-----	Not reported	**2nd Quarter** Annual inspection **4th Quarter** Follow-up inspection (if any) .
7	**M/s Human Biologicals Institute (A Division of**	Hepatitis B vaccine, Tetanus Toxoid vaccine (Adsorbed), DTP vaccine and Inactivated Rabies vaccine	12-13/February/2018 by CDSCO, State	Annual Inspection as per Central Inspection Plan-2018.	---	Observations Communicated to the firm for compliance	Not reported	**1st Quarter** Annual inspection **3rd Quarter**

Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2019

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	Indian Immunological Limtied) Rakshapuram, Gachibowli, Hyderabad-500019, TS		inspectors and expert from CDL, Kasauli			and to be verified in follow up inspection		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	02-03/Nov/2018 to, by CDSCO, State inspectors and expert from CDL, Kasauli	Annual Inspection as per Central Inspection Plan based on risk based approach & verification of GMP status as per Sch M requirements for Suite-A	As per report	Observations communicated to the firm for compliance and to be verified in follow up inspection	Not reported	**1st Quarter** Annual inspection **3rd Quarter** inspection (if any)
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)	21-22/Feb/2018 DI, CDSCO, state, Expert, CDL, Kasauli and AD, DCA, TS & DI, DCA, Hyd, TS.	Annual Inspection as per Central Inspection Plan-2018	As per report	Observations communicated 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)

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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	26 to 27 November 2018 by CDSCO, State inspectors and expert from CDL, Kasauli	For grant of COPP as per WHO-GMP certification scheme and routine inspection as per Central Inspection plan-2018.	As per report	No, compliance is to be submitted by the firm	Nil	**1st Quarter** Follow-up Inspection **3rd Quarter** Annual Inspection
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.	18-19/June/2018 by CDSCO, State inspectors and expert from CDL, Kasauli	1.) To verify the compliance status of firm with respect to observations noted in previous inspection dated 29 to 30 June 2017 as per Central Inspection Plan-2017. 2.) To verify the compliance status of firm with respect to observations noted in previous inspection dated 18 to 20 December 2017 for additional products approval in form 28-D.	As per inspection report	No, compliance is to be submitted by the firm	Nil	**1st quarter** Follow-up and **3rd quarter** Annual inspection
3	**M/s Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka-**	Inactivated Influenza vaccine(H1N1)	28/11/2018 Officials of CDSCO, FDCA,	For check compliance of subjected firm for 09 observations not complied during the compliance check inspection dated	As per inspection report	Complied	Nil	**2nd quarter** Annual inspection and **4th quarter** follow-up inspection

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	Ahmendabad, Gujarat		Gujarat and subject expert from CDL, Kasauli	20-21 June 2018 of previous routine inspection as per Central Inspection Plan dated 21-22 December 2017.				
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	22 to 23 Feb 2018 by CDSCO, State inspectors and expert from CDL, Kasauli	To verify the compliance of non-conformances reported in previous joint inspection dated 27 to 28 June 2017 for firm's positive results of endotoxins in 04 final batches of Rabipur lots specific for China as NIFDC China reported OOS result for BET and Pyrogen (B.no. 16021, 22, 23 and 24 and as per CIP-2018.	As per report.	The firm has complied 16 observations, partially complied 6 observation and not complied 03 observations noted in previous inspection.	Nil	**1st Quarter** follow up **3rd quarter** annual 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.**
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.**