



(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 2020**

Sr 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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<b>A NORTH ZONE</b>									
1	M/s. Biomed Pvt. Ltd, C-96, Site -I, Bulandshahar Road, Industrial Area, Ghaziabad, Uttar Pradesh	1. Oral Polio Vaccine IP, 2. Vi Polysaccharide Typhoid Vaccine (Bio Typh <sup>TM</sup> ) 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 <sup>TM</sup> ), 8. Haemophilus Type-B Conjugate Vaccine (PedaHib) IP 9. Meningococcal 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	18.11.2019 to 20.11.2019 ADC (I) and DIs of CDSCO and Uttar Pradesh	Compliance verification	As per Report	Observations communicated to the firm for compliance	---	<b>1<sup>st</sup> Quarter</b> Routine Inspection  <b>2<sup>nd</sup> quarter</b> Follow-up inspection (if any)  <b>3<sup>rd</sup> Quarter</b> Routine Inspection  <b>4<sup>th</sup> Quarter</b> Follow up inspection (if any)	



**(Refer SOP No. QA-INS-010)**  
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		Polysaccharide Vaccine (Group A,C,Y,W 135) QuadriMeningo , Nm Vac-4 ACYW135. 13. Veterinary Vaccines.						
2	M/s. Bharat Immunologicals & Biologicals Corporation Limited (BIBCOL), Village Chola, Dist. Bulandshahar, Uttar Pradesh.	Oral Poliomyelitis Vaccine IP	15/11/19 and 20/11/19 DIs of CDSCO and Uttar Pradesh	Compliance verification	As per Report	Observations communicated to the firm for compliance	NA	2 <sup>nd</sup> quarter Routine inspection  4 <sup>th</sup> Quarter Follow up inspection
3	M/s Panacea Biotech Limited, 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).	05/08/19 by CDSCO & State Inspector and expert from CDL, Kasauli.	1 <sup>st</sup> Quarter follow up inspection as per Central Inspection Plan-2019	As per report	Compliance report awaited	Not reported	1 <sup>st</sup> Quarter Annual inspection  3 <sup>rd</sup> Quarter Follow up 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™ 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)	18-19/09/19 by CDSCO, State Inspector & expert from CDL, Kasauli	Grant of License for monovalent Polio vaccine Type 1	As per report	Compliance report awaited	Not reported	2 <sup>nd</sup> Quarter Annual inspection	4 <sup>th</sup> Quarter Follow up inspection



(Refer SOP No. QA-INS-010)

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5	M/s Central Research Institute Kasauli, Distt. Solan (HP)	10. Hepatitis B vaccine (rDNA) BP (Enivac HB).						
B	SOUTH ZONE							
1	M/s. Green Signal Biopharma, Pvt. Ltd., No. 49, Pappankuppam Village, Gummidipoondi ,Chennai 601 201, Tamil Nadu.	1. BCG Vaccine (Freeze-Dried) IP/BP/EP/USP 2.BCG for immunotherapy (Freeze dried) BP/EPP	15/07/19 to 18/07/19 By CDSCO, state Drugs inspector and expert from CDL, Kasauli	1. Central Inspection Plan 2. Verification of WHO prequalification non compliances and 3. Verifying data of post approval changes 4. Compliance verification of previous inspection	As per Report	Observations communicated to the firm for compliance and to be verified in follow up Inspection.	Not reported	1 <sup>st</sup> Quarter Annual inspection  3 <sup>rd</sup> Quarter Follow up inspection  4 <sup>th</sup> Quarter Annual inspection



**(Refer SOP No. QA-INS-010)**  
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2	<b>M/s Human Biologicals Institute Kozhippanai, Pudumund Post, Udhagamandalam – 643 007 Tamil Nadu.</b>	Rabies Vaccine, Human IP, BP, Purified Rabies bulk antigen	16/10/19 to 18/10/19 by CDSCO and State Inspector and expert from CDL, Kasauli	1. Central Inspection Plan 2. Compliance verification for the risk based inspection conducted from 26th to 28th December 2018	As per Report	Observations communicated to the firm for compliance and to be verified in follow up Inspection.	Not reported	<b>3<sup>rd</sup> Quarter</b> Routine Inspection along with follow up inspection of the earlier inspection
3	<b>M/s. HLL Biotech Limited Integrated Vaccines Complex (IVC), Survey No. 192 &amp; 195, Thirumani Village, Thirukazhukundram (TK), Chengalpattu, Kanchipuram District - 603001, Tamil Nadu</b>	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)	09/03/18 to 10/03/18 by CDSCO and state Drugs Inspectors & 18/07/19 to 19/07/19 by CDSCO and State Drugs Inspector	1. To verify the readiness of the facility to supply vaccines for Universal Immunization Programme 2. Pharmacovigilance system inspection of site M/s. HLL Biotech Limited 3. HLL Biotech Limited has been issued manufacturing license No. TN0004800 dt; 04/12/2017 in Form 28D for labeling and packing of Hepatitis-B r-DNA & Pentavalent Vaccines naked vials procured from	Nil	Yes, compliance met	Not reported	<b>2<sup>nd</sup> quarter</b> Follow up Inspection  <b>4<sup>th</sup> quarter</b> Annual Inspection



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				Biological E Limited. However, the firm had not commenced labeling and packing activity so far. Therefore, risk based joint inspection as per CIP 2019 is not necessary of commercial batches. The reason for not conducting the inspection as per CIP 2019 was communicated to the directorate Vide letter no: 49-3(10)SZ/2019/1781-1782 dated 16/08/2019				
4	M/s. Venky Parenterals, Adavipolam, Yanam-533464, Tamil Nadu.	1. Tetanus Vaccine (Adsorbed) IP and 2. Adsorbed Tetanus Vaccine BP	15/10/18 to 16/10/18 by CDSCO and state drugs inspectors	Compliance verification for the previous inspection held on 09/11/2017 to 10/11/2017	NIL	Yes, compliance met	Not reported	4 <sup>th</sup> Quarter Annual inspection
5	M/s. BCG Vaccine lab, No. 110, 110A, 33 Feet Road, mount Road, Guindy	Freeze Dried BCG Vaccine I.P doses	27/09/18 to 29/09/18 by CDSCO and State inspectors and expert	1) Joint inspection for grant of manufacturing license in Form 28 D for the applied product "Freeze Dried BCG Vaccine IP" As firm has received	As per report	Yes, compliance met	Not reported	2 <sup>nd</sup> quarter Routine Inspection



**(Refer SOP No. QA-INS-010)**  
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	<b>Chennai-600032, Tamil Nadu.</b>		from CDL, Kasauli	License in Form 28D dated 19/09/2019. The annual inspection will be planned after commencing manufacturing of commercial batches.				
6	<b>M/s. Pasteur Institute of India, Nilgiris. Coonoor-643 103, Tamil Nadu.</b>	1. Diphtheria, Tetanus and Pertussis vaccine (Adsorbed) IP Triple vaccine 2. Diphtheria and Tetanus Toxoid (adsorbed)	14/10/19 to 15/10/19 by Central and State Drugs Inspectors and Expert from CDL, Kasauli	For issue of permission in CT-11 for manufacturing of test batches for test and analysis (pre-clinical Toxicological studies only) and compliance verification of previous joint inspection dated 28-03-2019 to 29-03-2019	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 manufacturing Licence in form 28-D
<b>C WEST ZONE</b>								
1	<b>M/s. Serum Institute of India Ltd, 212/2 Hadapsar, Pune-411028, Maharashtra.</b>	TT, DT, DPT, Rabies, Hib, Meningococcal A Conjugate vaccine, Influenza vaccine, BCG, Measles, Rubella, MMR, flu vaccine for TT,DTP, HiB, DTP, HiB/Hep.B, Rabies vaccine, H1N1	10/12/2019 & 13/12/2019 by CDSCO and State inspectors and expert from CDL, Kasauli	1) Central inspection plan using risk based Approach [4 <sup>th</sup> Quarter Annual Inspection] 2) For grant of drug manufacturing license in Form 28D	As per Report	Observations communicated to the firm for compliance	AEFI reported by the firm in the year 2019 1) Measles & Rubella Vaccine – Indonesia (01 case) 2) Pentavalent	2 <sup>nd</sup> Quarter Routine Inspection 4 <sup>th</sup> Quarter Follow up Inspection



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							Vaccine – Vietnam (01 case) 3) MMR Vaccine – Cuba (01 case) 4) BCG Vaccine – Indonesia (01 case)	
2	M/s. Haffkine Biopharmaceutical Corporation Ltd. (HPCL), Parel, Mumbai, Maharashtra.	OPV	17/07/2019 & 18/07/2019 by team of CDSCO, State inspectors and expert from CDL, Kasauli	Routine and compliance verification as per 4 <sup>th</sup> Quarter Central Inspection Plan	As per Report	Observations communicated to the firm for compliance	Nil	2 <sup>nd</sup> Quarter Follow up and Routine Inspection
3	M/s. Bio Vaccines (India) Pvt Ltd., 46-A, Sanwar Road, Industrial Area, Indore- 452015,	Tetanus Vaccine (Adsorbed) IP 0.5 ml (single dose) & 5.0 ml (multiple dose)	19.08.2019 By team of CDSCO, state licensing authority	Post approval change (Grant of manufacturing license in Form 28D for Tetanus Vaccine (Adsorbed) IP 0.5 ml (single dose))	Nil	Observations communicated to the firm for compliance	Nil	3 <sup>rd</sup> quarter Routine Inspection



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	<b>Madhya Pradesh.</b>							
<b>D</b>	<b>HYDERABAD ZONE</b>							
1	<b>M/s. Bharat Biotech International Ltd. Genome Valley, Turkapally Shameerpet (Mandal) Hyderabad-500078. Telangana State.</b>	Hepatitis B vaccine, VI Polysaccharide Typhoid vaccine, Hib, DTP+Hib+Hep, Rabies vaccine, oral polio vaccines(tOPV), oral rotavirus vaccines	27/11/2019 to 28/11/2019 by CDSCO, State inspectors and expert from CDL, Kasauli	1. For verification of additional facility PF1 proposed for manufacture of test batches of bOPV Type1 & 3 under Form-29. 2. For verification w.r.t destruction of rabies Vaccine, Human B.No. 62E19008A, Mfg Dt: 03/19, Exp Dt:01/22.	As per report	Observations communicated to the firm for compliance and to be verified in follow up inspection	05 batches of NSQ for Rotavac vaccine were found.	<b>1<sup>st</sup> Quarter</b> Routine Inspection  <b>3<sup>rd</sup> Quarter</b> Follow-up inspection
2	<b>M/s. Biological E. Limited 7-4-34 Gaganpahad Rajendra Nagar Mandal, R.R., Dist., Telangana State.</b>	Tetanus vaccine(adsorbed)(Bulk), Diphteria antitoxin 1000 IU(Bulk), Diphteria antitoxin 20,000 IU(Bulk), Tetanus antitoxin (Bulk)	26/08/19 to 28/08/19 by CDSCO and State inspectors and expert from CDL, Kasauli	1. For Annual Routine GMP Inspection as per Central Inspection Plan-2019 based on risk based approach-2 <sup>nd</sup> quarter. 2. For Verification of CAPA submitted by firm against the annual audit carried out on 04-05/06/2018 as per CIP-2018 based on risk based approach. 3. For grant of manufacturing	Nil	Observations communicated to the firm for compliance and to be verified in follow up inspection.	Not reported	<b>2<sup>nd</sup> Quarter</b> Routine Inspection  <b>4<sup>th</sup> Quarter</b> Follow-up inspection



**(Refer SOP No. QA-INS-010)**  
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3	M/s. Biological E. Limited 18/1 & 3,Azamabad, Hyderabad, Telangana State.	Tetanus vaccine (adsorbed), DTP vaccine (adsorbed), DT vaccine (adsorbed), Tetanus antitoxin, Diphteria antitoxin, JE inactivated vaccine	04/11/19 to 06/11/19 by CDSCO, State inspectors and expert from CDL, Kasauli	license in Form- 28-D for five additional product (Anti sera bulk for lyophilisation)  1. Follow up GMP inspection as per Central inspection plan-2019 & CAPA verification of previous inspection. 2. For the grant of additional product (Snake antivenin IP) in Form-28D	As per report	Observations communicated to the firm for compliance and to be verified in follow up Inspection.	Not reported	2 <sup>nd</sup> Quarter Routine Inspection  4 <sup>th</sup> Quarter Follow-up inspection
4	M/s. Biological E. Limited, Plot no. 1, SP Biotechnology Park Phase II, Kolthru village, Shamarpheet, Madal, Ranga Reddy, Dist., Telangana State.	DTPw (Whole cell), Diphteria, Pertusis Hepatitis B vaccine bulk, JE Vaccine, TT, Hepatitis B, DTP+ Hep+Hib	04/11/19 to 17/11/19 by CDSCO, State inspectors and expert from CDL, Kasauli	1. For Annual Routine Inspection as per Central Inspection Plan-2019 & CAPA verification of previous inspection 2. For grant of additional product (13 products) in Form-28D 3. CAPA verification against audit carried out on 21.08.2017 for grant of Form29 NOC for the product Typhoid vaccine Bulk Conjugate (Vi-CRM197), Paratyphoid A Vaccine Bulk Conjugate	Nil	Observations communicated to the firm for compliance and to be verified in follow up inspection	NSQ for the liquid penta valent vaccine B.No: 220106717A was verified and found to be of standard quality.	2 <sup>nd</sup> Quarter Routine Inspection  4 <sup>th</sup> Quarter Follow-up inspection



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				<p>(O:2-CRM1970), Poliomyelitis vaccine(inactivated) and inactivated hepatitis A vaccine (Adsorbed)</p> <p>4. CAPA verification against audit carried on 30.10.2018 for grant of Form 29 NOC for the products for Antisera products (AntiSnake Venom-08 products)</p> <p>5. Post approval changes made during 2017 (Total 08 changes)(ref-2)</p> <p>6. CAPA verification against audit carried 29/10/2018 and 30/10/2018 for grant of Form 29 NOC for the products for Acellular pertussis Antigen Bulk</p>				
5	M/s. Dano Vaccines & Biological Pvt. Limited, 575, Sivareddygud, Ghatkesar Mandal, 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	07/11/19 to 09/11/19 DI, CDSCO-HQ, DI-CDSCO Hyd, expert CDL Kasauli and	<p>1. For annual routine inspection as per Central Inspection Plan-2019 (follow up inspection) &amp; CAPA verifications of previous inspections.</p> <p>2. For CAPA verification against the annual audir</p>	As per report	Observations communicated to the firm for compliance and to be verified in	Not reported	<p><b>1<sup>st</sup> Quarter</b> Routine Inspection</p> <p><b>3<sup>rd</sup> Quarter</b> Follow-up inspection (if any)</p>



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	<b>Telangana State.</b>		DI DCA	<p>carried out on 06.03.2017 to 08.03.2017 as per Central Inspection Plan-2017 and annual audit carried out on 14.06.2018 to 15.06.2018 as per Central Inspection Plan-2018 and annual audit carried out on 20.06.2019 to 22.06.2019 as per Central Inspection Plan-2019 based on Risk based approach.</p> <p>3. For CAPA verification against the investigation carried out on 16.01.2018 to 17.01.2018 and 31.01.2018 to 01.02.2018</p>		follow up Inspection.		
6	<b>M/s Human Biologicals Institute Survey No. 281 to 284 and 321, Karakapatla (V), Medak 502281,</b>	Inactivated Rabies Vaccine	29/08/19 to 30/08/19 by CDSCO, State inspectors and expert from CDL, Kasauli	For Annual Routine Inspection GMP as per Central Inspection Plan-2019 based on Risk based approach	Nil	Observations communicated to the firm for compliance	Not reported	<b>1<sup>st</sup> Quarter</b> Routine Inspection  <b>3<sup>rd</sup> Quarter</b> Follow-up inspection (if any)



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	<b>Telangana State.</b>							
7	<b>M/s Human Biologicals Institute (A Division of Indian Immunological Limited) Rakshapuram, Gachibowli, Hyderabad-500019, Telangana State.</b>	Hepatitis B vaccine, Tetanus Toxoid vaccine (Adsorbed), DTP vaccine and Inactivated Rabies vaccine	26/08/19 to 28/08/19 by CDSCO, State inspectors and expert from CDL, Kasauli	1. Follow up GMP inspection as per Central Inspection Plan-2019. 2. CAPA verification for the joint inspection dated 22/04/2019 to 24/04/2019 for the grant of additional product in Form 28-D, hepatitis b vaccine (rDNA) – ready to fill bulk 3. CAPA verification for the audit observations made during joint inspection for grant of Form-29 NOC to manufacture DPT (Whole cell), hepatitis B (rDNA) and Haemophilus influenza type b conjugate and inactivated poliomyelitis vaccine (Adsorbed) 4. For verification of post	Nil	Observations Communicated to the firm for compliance and to be verified in follow up inspection	Not reported	<b>1<sup>st</sup> Quarter</b> Routine Inspection  <b>3<sup>rd</sup> Quarter</b> Follow-up inspection (if any)



**(Refer SOP No. QA-INS-010)**  
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8	M/s. Shantha Biotechnics Ltd. Survey No. 274, Arthvelli Village, MedchalMandal , Ranga Reddy District-501401, Andhra Pradesh.	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	17/06/2019 to 19/06/2019, by CDSCO, State inspectors and expert from CDL, Kasauli	approval annual changes made during January 2018 to December 2018  1. For Annual Inspection as per Central Inspection Plan-2019 2. Verification of supporting documents of Post approval changes submitted to O/o. DDC(I) under Annual Notifications (period January 2018 to December 2018)	Nil	Observations communicated to the firm for compliance and to be verified in follow up inspection	Not reported	<b>2<sup>nd</sup> Quarter</b> Routine Inspection  <b>4<sup>th</sup> Quarter</b> Follow-up inspection (if any)
9	M/s. Shantha Biotechnics Ltd., Sy. No. 354, Muppireddypally (V), Toopran (M), Medak Dist, Telangana State.	Cholera Vaccine (inactivated oral), DTP (whole cell), Hepatitis-B (rDNA) & Hib Conjugate Vaccine (Adsorbed)	08/11/2019 to 09/11/2019 DI, CDSCO, state, Expert, CDL, Kasauli and AD, DCA, TS & DI, DCA, Hyd, TS.	1. Annual Inspection as per Central Inspection Plan-2019 and CAPA verifications of previous inspection  2. Restart notification of suite 2A after maintenance shutdown  1. CAPA verification against audit carried on 21/02/2018 and 22/02/2018 for grant of additional product in Form 28D [ShanIPV-Filling and	Nil	Observations communicated to the firm for compliance and to be verified in follow up inspection	Not reported	<b>2<sup>nd</sup> Quarter</b> Routine Inspection  <b>4<sup>th</sup> Quarter</b> Follow-up Inspection



(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 2020**

Sr 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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1	M/s Cadila Healthcare Limited, Sarkhej- Bayla, NH-8A, Village Moraiya, Dist. Ahmedabad Gujarat.	1. Rabies Vaccine (Purified Chick Embryo Cell Culture Rabies Vaccine (PCECV)) Vaxirab-N	16/07/19 to 17/07/19 Officials of CDSCO and FDCA, Gujarat	For compliance check inspection of previous inspection dated 26 to 27 November 2018 for grant of COPP as per WHO-GMP certification scheme and routine inspection as per Central Inspection plan	As per report	No, compliance is to be submitted by the firm	Nil	<b>1<sup>st</sup> Quarter</b> Routine Inspection

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Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2020

Sr 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
2	M/s Cadila Healthcare Ltd. Village Changodhar, Tal Sanand, Dist Ahmedabad 382 213, Gujarat.	1. Inactivated influenza vaccine (split virion) I.P. (tetravalent) 0.25 ml 2. Inactivated influenza vaccine (split virion) I.P. (tetravalent) 0.5 ml 3. Tetanus Vaccine (Adsorbed) I.P. 4. Bulk Purified Tetanus Toxoid 5. Measles Vaccine (Live) I.P. (Freeze Dried)- Single dose 6. Diphteria, Tetanus & Pertusis (Whole Cell) Vaccine (Adsorbed) I.P. 7. Inactivated influenza vaccine (split virion) I.P. (trivalent) 0.5 ml	14/10/19 to 16/10/19 Officials of CDSCO, FDCA, Gujarat and subject expert from CDL, Kasauli	Follow-up and Routine inspection as per CIP	As per report	No, compliance is to be submitted by the firm	Nil	<b>1<sup>st</sup> quarter</b> Follow-up inspection  <b>4<sup>th</sup> quarter</b> Routine inspection
3	M/s Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka- Ahmedabad, Gujarat.	1. Monovalent Influenza A (H1N1 2009) VLP Vaccine (CadiFlu) 2. Trivalent Seasonal Influenza VLP (CadiFlu S)	17/10/19 & 18/10/19 Officials of CDSCO, FDCA, Gujarat and expert from CDL, Kasauli	Routine inspection as per CIP	As per report	No, compliance is to be submitted by the firm	Nil	<b>2<sup>nd</sup> quarter</b> Follow-up and Routine inspection



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Central Inspection Plan Using Risk Based Approach Of Vaccine Manufacturing Units for 2020

Sr 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
4	M/s Chiron Behring Vaccine Ltd., Plot No. 3502, GIDC Estate, P.O. 136, Ankleshwar, Gujarat.	1. Rabies Vaccine	28/11/2019 Officials of CDSCO and FDCA, Gujarat and expert from CDL, Kasauli	For compliance check of previous inspection dated 23 to 24 September 2019 for grant/renewal of COPP as per WHO-GMP certification scheme.	As per report	Complied	Nil	3 <sup>rd</sup> 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.
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.