

(Refer SOP No. QA-INS-012)

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 r-DNA products Manufacturing Units for 2020

Sl. No.	Name and address of the manufacturing site	r-DNA products manufactured (category wise list)	Dt. of last inspection with no of days & team	Purpose of last inspection (grant /renewal /post-approval changes, follow-up, routine)	Major deficiencies detected	Compliance met till date, if any	Changes/ Product complaints, failure if any	Proposed time of Inspection
A	SOUTH ZONE, CHENNAI							
1	Levim Biotech LLP Ticel Biopark Phase II, 501-505, CSIR Road, Taramani, Chennai-600113	Streptokinase Bulk Solution (r-DNA) under manufacturing license in Form 28 D bearing No. TN00004249 dated 31.10.2016	16-12-2019 to 18-12-2019 3 days Drugs inspector of CDSCO & SLA	Central Inspection Plan using Risk based approach, CIP 2019 and post approval change and compliance verification of previous inspection	As per report	Inspection is conducted in the month of December - 2019 and the report is under preparation.	Not reported	4th Quarter Annual inspection along with follow up inspection.
B	WEST ZONE, MUMBAI							
1	M/s. Lupin Ltd., (Biotech Division), Gat No. 1156 (Part), Vill. Ghotawade, Tal: Mulshi, Dist: Pune - 412115 (Lic. No - PD/Vacc/12)	Filgrastim, Peg Filgrastim	27-05-2019 to 28-05-2019 Drugs inspector of CDSCO	For renewal of WHO-GMP Certificate.	As Per Report	As Per Report	--	4th Quarter [02 days]

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2	M/s. Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune - 411028, Maharashtra, India (Lic. No – 10)	1.Erythropoietin Injection 2. Rabies Human Monoclonal Antibody 3. Recombinant CRM 197 Bulk	10-12-2019 to 13-12-2019 Drugs inspector of CDSCO along with expert	Central Inspection plan using Risk Based approach (4 th quarter annual inspection)	As Per Report	As Per Report	--	4th Quarter [02 Days]
3	M/s. Wockhardt Ltd., Biotech Park, H-14/2A, MIDC, Waluj, Aurangabad. (Lic. No – AD/004)	Insulin, Erythropoietin, Insulin Glargine	14-02-2019 to 15-02-2019 Drugs inspector of CDSCO	For renewal of WHO-GMP Certificate.	As Per Report	As Per Report	--	4th Quarter [02 Days]
4	M/s. Genova Biopharmaceutical Ltd., Plot No. P-1, ITBT Park, Phase II, MIDC, Hinjawadi, Pune – 411057 (PD/Vacc – 6)	A) Liquid Injectable: 5 l. Erythropoietin injection IP/BF 2. Filgrastim Injection (GCSF) IP 3. Pegfilgrastim injection 4. Pegaspargase Injection (PD/ I 1 8) 5. Enoxaparin Injection IP (PD/I18) B) Lyophilized Powder for Injection: 2 l. Recombinant Tissue Plasminogen Activator (TNK-tpA) Injection 2. Recombination Granulocyte Macrophage	24-04-2019 - 26-04-2019 Drugs inspector of CDSCO	For renewal of WHO-GMP Certificate.	As Per Report	As Per Report	--	3rd Quarter [02 Days]

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		Stimulating Factor Injection (CMCSIT) C) Bulk Drug: 3 I. Erythropoietin Concentrated Solutionlp/ph.Eur 2. Tenecteplase Bulk 3. Pegaspargase bulk (PD/118)						
5	M/s. USV Ltd., H-17/H-18, OI DC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman(DD/716)	Somatropin for injection Ph. Eur. Pegfilgrastim solution for injection. Teriparatide Injection 750mcg/3ml	29-07-2019 to 31-07-2019 Drugs inspector of CDSCO & SLA	For renewal of WHO-GMP Certificate.	As Per Report	As Per Report	--	4th Quarter [02 Days]
6	M/s. Shreya Life Sciences Pvt. Ltd., B-9/2, MIDC, Waluj, Aurangabad - 431136. (28D – AD/006)	Insulin Formulation	19-02-2019 to 20-02-2019 Drugs inspector of CDSCO	For renewal of WHO-GMP Certificate	As Per Report	As Per Report	--	3rd Quarter [02 Days]
7	M/s. Scigen Biopharm Pvt. Ltd., Plot No. 18, International Biotech Park, Hinjewadi, Phase-II, Pune - 411057. PD/Vacc/14	Recombinant Human Insulin Ph. Eur/I.P	29-10-2019 Drugs inspector of CDSCO & SLA	For grant of WHO-GMP Certificate.	As Per Report	As Per Report	--	3rd Quarter [02 Days]

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C	HYDERABAD ZONE							
1	M/s. Dr. Reddy's Laboratories Ltd., Sy No. 47, Bachupally (V), Quthubullapur (M), R.R.Dist, TS	Rituxiamb, Darbepoetin Alfa, Pegfilgrastim, Filgrastim and Trastuzumab	09-10-2019 to 10-10-19 Drugs inspector of CDSCO & SLA along with expert	For annual routine GMP inspection as per CIP-2019	As Per Report	As Per Report	--	1st Quarter Annual inspection 3rd Quarter Follow-up Inspection (if any)
2.	M/s. Hetero Biopharma Ltd, Unit-III, Sy. No. 458 (part), TSIIC Pharma SEZ, Polepally (V), Jadcharla (M), Mahaboobnagar Dist- 509301, TS.	Darbepoetin alfa Injection, Rituximab, Bevacizumab, Adalimumab, Trastuzumab, Emtansine, Denosumab and Tenecteplase	24-09-2019 to- 25-09-19 Drugs inspector of CDSCO & SLA along with expert	For annual routine GMP inspection as per CIP-2019	As Per Report	As Per Report	--	1st Quarter Annual inspection 3rd Quarter Follow-up Inspection (if any)
3.	M/s. Bharat Biotech International Ltd., Genome Valley, Turkapally, Shameerpet	Hepatitis B Vaccine, Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) vaccine (Adsorbed), Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) and Haemophilus	03-10-2019 to 04-10-19 Drugs inspector of CDSCO & SLA along	For annual routine GMP inspection as per CIP-2019	As Per Report	As Per Report	--	2nd Quarter Annual inspection 4th Quarter Follow-up Inspection (if any)

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	(Mandal), Hyderabad- 500078, T.S.	influenzae Type b Conjugate vaccine (Adsorbed), Recombiant Human Epidermal growth factor gel and silver sulfadiazine, chlorhexidine gluconate and recombinant human epidermal growthfactor cream	with expert					
4	M/s. Sudershan Biotech Limited, 4-100, C/9 & C/10, L. B. Nagar, Hyderabad.	Recombinant HIV Antigen p24, Recombinant HIV Antigen gp41 and Recombinant HIV Antigen gp120	Inspection proposed and post punned due to non-availability of Subject Expert. Inspection proposed on 06-07-01-2020	For annual routine GMP inspection as per CIP-2019	As Per Report	As Per Report	--	2nd Quarter Annual inspection 4th Quarter Follow-up Inspection (if any)
5	M/s. Gland Pharma Limited, Sy.No. 143-148, 150 & 151, Near Gandimaisamma Cross Road, D.P Pally, Dundigal post, Qutbullapur, Rangareddy, TS	Human Insulin	Inspection proposed and post punned due to non-availability of Subject Expert. Inspection proposed on 08-10-01-2020	For annual routine GMP inspection as per CIP-2019	As Per Report	As Per Report	--	2nd Quarter Annual inspection 4th Quarter Follow-up Inspection (if any)

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D AHMEDABAD ZONE								
1.	M/s. Cadila Healthcare Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Sarkhej-Bavla N/H No. 8A, Opp: Ramdev Masala, Village: Changodar, Tal: Sanand, Dist. Ahmedabad-382213, India.	r-DNA Products as approved by Licensing Authority	07-08-2019 to 09-08-2019 Drugs inspector of CDSCO & SLA along with expert	Routine Inspection as per CIP-2019	As per Report	Observations communicated to the firm for compliance. To be verified in follow-up inspection	Not Reported	2nd Quarter Follow up Inspection 4th Quarter Annual Inspection
2	M/s. Torrent Pharmaceuticals Ltd., Ahmedabad-Mehsana Highway, Indrad, Tal. Kadi, Dist.: Mehsana, India.	1. Human Actrapid 40 IU/ml (Soluble Insulin Injection IP) 2. Human Insulatard 40 IU/ml (Isophane Insulin Injection IP) 3. Human Mixtard 40 IU/ml (Biphasic Isophane Insulin Injection IP) 4. Human Mixtard 50 40 IU/ml (Biphasic Isophane Insulin Injection IP) 5.	5-08-2019 to 6-08-2019 Drugs inspector of CDSCO & SLA along with expert	Routine Inspection as per CIP-2019	As per Report	Observations communicated to the firm for compliance. To be verified in follow-up inspection	Not Reported	3rd Quarter Annual along with follow up Inspection

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3	M/s Cadila Pharmaceuticals Limited, 1389, Dholka, District, Ahmedabad, Gujarat State, India	1. Insulin Injection IP 40 IU 2. Isophane Insulin Injection IP IU 3. Biphasic Isophane Insulin Injection IP30/70 4. Insulin Injection Soluble PhEur 5. Recombinant Human Granulocyte Colony Stimulating Factor Injection (Filgrastim Injection) 6. Recombinant Human Erythropoietin injection IP 2000 IU/4000 IU 7. Recombinant Human Erythropoietin concentrate solution bulk IP/BP	23-12-2019 to 24-12-2019 Drugs inspector of CDSCO & SLA along with expert	Routine Inspection as per CIP-2019	As per Report	Observations communicated to the firm for compliance. To be verified in follow-up inspection	Not Reported	2 nd Quarter Annual along with follow up inspection
4	M/s Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Balva Highway, Moraiya, Tal-Sanand, Ahmedabad-382213, Gujarat, India	r-DNA Products as approved by Licensing Authority	22-08-2019 to 23-08-2019 Drugs inspector of CDSCO & SLA along with expert	Routine Inspection as per CIP-2019	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

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E								
Bangalore SubZone								
1.	M/s. Biocon Limited, 20 th K M, Hosur Road, Electronics City, Bengaluru-560100	1. Insulin Human Bulk (r-DNA origin), IP/USP/Ph. Eur. 2. Insulin Glargine (r-DNA)-Bulk. In-house/Ph. Eur. 3. Recombinant Human granulocyte colony stimulating factor (Filgrastim)- Bulk 4. Pegfilgrastim (r-DNA origin) Bulk (for export purpose only) 5. Recombinant Streptokinase - Bulk	01-08-2019 to 02-08-2019 Drugs inspector of CDSCO & SLA along with expert	Central annual Inspection with respect to Directorate office memorandum vide File No. QA/01/Central Inspection Plan/ rDNA/ 2019/ CT dated 29.01.2019	As per Report forwarding Letter no. ADC/BSZ/KT K/ rDNA/2019-20/1143 dated 26.09.2019	Joint inspection report forwarded to Directorate for further necessary action and copied to DC, Karnataka.	Not reported	3rd Quarter Annual Inspection 4th Quarter follow up Inspection (If any)
2	M/s. Biocon Limited, Special Economic Zone Plot No. 2, 3, 4 and 5, Phase IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bengaluru-560099	1. Insulin Injection (rDNA Origin) 2. Insulin Glargine Injection (rDNA Origin) 3. Trastuzumab (r-DNA Origin) - bulk and its formulations 4. Trastuzumab (PGS - bulk and formulations)-export purpose only 5. Bevacizumab (r-DNA Origin) - bulk and its formulations	05-08-2019 to 06-08-2019 Drugs inspector of CDSCO & SLA along with expert	Central annual Inspection with respect to Directorate office memorandum vide File No. QA/01/Central Inspection Plan/ rDNA/ 2019/ CT dated 29.01.2019	As per Report forwarding Letter no. ADC/BSZ/KT K/ rDNA-Biocon/2019-20/1013 dated 13.09.2019	Joint inspection report forwarded to Directorate for further necessary action and copied to DC,	Not reported	3rd Quarter Annual Inspection 4th Quarter follow up Inspection (If any)

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		6. Pegfilgrastim (r-DNA origin) formulations-export purpose only 7. Recombinant Human Erythropoietin Injection 8. Recombinant Streptokinase Injection 9. Humanized Anti-EGFR Monoclonal Antibody (Nimotuzumab)-bulk and its formulations 10. Itolizumab (T1hmAb) (r-DNA) - bulk and its formulations 11. Itolizumab Injection				Karnataka.		
3.	M/s Kemwell Biopharma Private limited , 34th KM, Tumkur Road, T- Begur, Nelamangala, Bangalore – 562123, India	Rituximab (r-DNA origin) 10ml vial, 10mg/ml	19-08-2019 to 20-08-2019 Drugs inspector of CDSCO & SLA along with expert	Central annual Inspection with respect to Directorate office memorandum vide File No. QA/01/Central Inspection Plan/ rDNA/ 2019/ CT dated 29.01.2019	As per Report forwarding Letter no. ADC/BSZ/KT K/ rDNA- Kemwell/2019-20/1347 dated 23.10.2019	Joint inspection report forwarded to Directorate for further necessary action and copied to DC, Karnataka.	Not reported	3rd Quarter Annual Inspection 4th Quarter follow up Inspection (If any)

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4.	M/s. Mylan Laboratories Limited (Sterile Product Division) Opp. IIM, Bilekahalli, Banneraghatta Road, Bangalore – 560076	Adalimumab 40 mg/0.8 mL solution for Injection Pegfilgrastim 6 mg/0.6 mL Injection	07-08-2019 to 08-08-2019 Drugs inspector of CDSCO & SLA along with expert	Central annual Inspection with respect to Directorate office memorandum vide File No. QA/01/Central Inspection Plan/ rDNA/ 2019/ CT dated 29.01.2019	As per Report forwarding Letter no. ADC/SZB/KT K/ rDNA- Mylan/2019-20/1037 dated 13.09.2019.	Observation communicate to the firm and the compliance report was submitted by the firm vide their application dated 25.10.2019 with the copy marked to DCG(I) and DC, Karnataka.	Not reported	3rd Quarter Annual Inspection 4th Quarter follow up Inspection (If any)

Note:

1. 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.