



(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 2019

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	<u>SOUTH ZONE, CHENNAI</u>							
1	M/s 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	17.12.2018 to 19.12.2018 3 days by central, state Drugs Inspectors.	For Grant of NOC to obtain Form 29 license to manufacture examination, test and analysis.	As per report	Observations Communicated to the firm for Compliance To be verified in follow up Inspection.	Not reported	3rd Quarter Annual inspection along with follow up of earlier inspection.
B	<u>WEST ZONE, MUMBAI</u>							
1	M/s. Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center, R-282, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai - 400701. (Lic.No.KD/07)	1.Abciximab Inj & Bulk 2.Adalimumab Inj & Bulk 3.Bevacizumab Inj & Bulk 4.Choriogonadotropin alfa Inj. & Bulk 5.Darbepoetin alfa Inj & Bulk 6.Erythropoietin Inj. & Bulk 7. Etanercept for Inj & Bulk 8. Filgrastim Inj & Bulk 9. Infliximab Powder for concentrate for solution for infusion. 10. Interferon Alpha 2b Inj & Bulk. 11. Interferon beta 1a Inj & Bulk. 12.Pegfilgrastim (Peg-GCF) Inj. & Bulk 13.Recombinant Follicle Stimulating Hormone Inj. & Bulk 14.Recombinant Tissue Plasminogen	12/06/2018 Shri. Manish Singhal, DI, CDSCO, WZ, Mumbai Ms. Sapana Ghunkikar, DI, FDA, Maharashtra.	For grant of mfg. lic. For commercial purpose Recombinant Human Growth Hormone (Somatropin) drug substance (Bulk) (4-8 mg/mL), Recombinant Human Growth (Somatropin) Injection	As Per Report	As Per Report	--	3rd Quarter Annual inspection along with follow up of earlier inspection (If any)



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		Activator (Reteplase) Inj. Kit 15.Rituximab Inj & Bulk 16.Tenecteplase (TNK-tPA) for Inj & Bulk 17.Trastuzumab for Inj & Bulk 18.Recombinant Human Growth Hormone (Somatropin) Inj & Bulk.						
2	M/s. Bharat Serum and Vaccine Ltd., Plot No. K-27. Jambivli Village, Anandnagar, Additional MIDC, Ambernath (E), Thane – 421501 (Lic.No – KD/4)	1. Recombinant - Human Follicle Stimulin8 Hormone for injection - Freeze Dried & Bulk	26/11/2018 to 28/11/2018 Shri. Manish Singhal & Shri. Popat Thorat, DI (s), CDSCO, West Zone, Mumbai. Dr. A. M. Manikrao, DI, FDA,Thane	For renewal of COPP under WHO-GMP certification & Retention of License in Form 28-D	As Per Report	As Per Report	--	3rd Quarter Annual inspection along with follow up of earlier inspection (If any)
3	M/s. Lupin Ltd., (Biotech Division), Gat No. 1156 (Part), Vill. Ghotawade, Tal: Mulshi,	Filgrastim, Peg Filgrastim	11 & 12/09/2018 Shri. Manish Singhal, DI, CDSCO, WZ,	For renewal of license in Form 28-D	As Per Report	As Per Report	--	4th Quarter Annual inspection along with follow up of earlier inspection (If any)



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	Dist: Pune – 412115 (Lic. No – PD/Vacc/12)		Mumbai. Shri. P M Patil, DI, FDA, Pune.					
4	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	03 & 04/10/2018 Dr. Vijai Singh Karwasara & Shri. Manish Singhal, DI(S), CDSCO, West Zone, Mumbai. Smt. Bhagyashree Yadav, DI, FDA, Pune. Shri. Sushil Kumar Sahu, Expert, CDL, Kasauli.	For NOC for grant of additional product approval in Form 28D for Pneumococcal Polysaccharide Vaccine (Adsorbed) [10 Valent] for Export	As Per Report	As Per Report	--	4th Quarter Annual inspection along with follow up of earlier inspection (If any)



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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
5	M/s. Wockhardt Ltd., Biotech Park, H-14/2A, MIDC, Waluj, Aurangabad. (Lic. No – AD/004)	Insulin, Erythropoietin, Insulin Glargine	04/08/2017 Dr. Naveen Mehta and Shri. Amol E. Kandekar, DI (S), CDSCO, WZ, Mumbai. Shri. Pravin Harak, DI, FDA, Aurangabad.	For separation & grant of New License to r-DNA API facility.	As Per Report	As Per Report	--	2nd Quarter Annual inspection along with follow up of earlier inspection (If any)
6	M/s. Gennova Biopharmaceutical Ltd., Plot No. P-1, ITBT Park, Phase II, MIDC, Hinjawadi, Pune – 411057 (PD/Vacc – 6)	A) Liquid Inject able: 5 l. Erythropoietin injection IP/BP 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 1. Recombinant Tissue Plasminogen Activator (TNK-tpA) Injection 2. Recombination Granulocyte Macrophage Stimulating Factor Injection (CMCSIT) C) Bulk Drug: 3 l. Erythropoietin Concentrated Solutionlp/ph.Eur 2. Tenecteplase Bulk 3. Pegaspargase bulk (PD/I 18)	24 & 25/10/2016 Shri. Naveen Yadav, DI, CDSCO, WZ, Mumbai. Dr. Vijai Singh Karwasara, DI, CDSCO, WZ, Mumbai. Shri. D. M. Khivasara, DI, FDA, Pune.	For renewal of mfg. Lic. In Form 28-D	As Per Report	As Per Report	--	3rd Quarter Annual inspection along with follow up of earlier inspection (If any)



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			Dr. Sanjay Nene, Ex-Chief Scientist, National Chemical Laboratory (NCL), Pune					
7.	M/s. USV Ltd., H-17/H-18, OIDC, Mahatma Gandhi Udyog Nagar, Dabhel, Daman (DD/716)	Somatropin for injection Ph. Eur. Pegfilgrastim solution for injection. Teriparatide Injection 750mcg/3ml	27/06/2014 Shri. V Kaviyaran, DI, CDSCO, WZ, Mumbai. Shri. Girish Vaghela, DI, FDA, Daman. Dr. Robin Mukhopadhyay, Technical Expert, Mumbai	For grant of Mfg. Lic in Form 28-D for mfg. of r-DNA Product Somotropin Concentrated Solution Ph. Eur.	As Per Report	As Per Report	--	4th Quarter Annual inspection along with follow up of earlier inspection (If any)



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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
8	M/s. Shreya Life Sciences Pvt. Ltd., B-9/2, MIDC, Waluj, Aurangabad - 431136. (28D - AD/006)	Insulin Formulation	15/10/2015 Shri. Sushanta Sarkar, DI, CDSCO, WZ, Mumbai. Shri.Dhanan jay Sable, DI, CDSCO, WZ, Mumbai.	For renewal of manufacturing license.	As Per Report	As Per Report	--	3rd Quarter Annual inspection along with follow up of earlier inspection (If any)
9.	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	16/02/2015 Shri. Gourishank ar, DI, CDSCO, WZ, Mumbai. Smt. Dinesh Khivasara, DI, FDA, Pune. Dr. R Mukhopadh yay, Technical	For grant of manufacturing license in Form 28-D for manufacture of r-DNA (Recombinant Human Insulin Ph. Eur/I.P (Bulk)	As Per Report	As Per Report	--	3rd Quarter annual inspection along with follow up of earlier inspection (If any)



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			Expert, Scientist Grade II [Formerly ACTREC, Tata Memorial Centre, Mumbai.]					
10	M/s. M J Biopharm Pvt. Ltd., Plot No. 1, L-7, MIDC Industrial Area, Taloja, Dist: Raigarh, Navi Mumbai - 410208. KD-6	Recombinant Human Insulin Formulation.	28/07/2014 Shri. Gourishankar, DI, CDSCO, WZ, Mumbai. Shri. V B Taskedkar, DI, FDA, Thane. Dr. R Mukhopadhyay, Technical Expert, Scientist Grade II,	Mfg. step viz. filling of formulations, Recombinant Human Insulin	As Per Report	As Per Report	--	4th Quarter Annual inspection along with follow up of earlier inspection (If any)



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			(Formerly ACTREC Tata Memorial Centre)					
11	M/s. USV Ltd., D-115,TTC Industrial area, Shirvane - 400706 Tal - Nerul (KD/11)	Pegfilgrastim concentrated solution Ph.Eur Teriparatide Concentrated Solution Ph.Eur Somatotropin concentrated solution (Bulk API)	04/10/2016 & 05/10/2016 Shri. Arunachalam, DI, CDSCO, WZ, Mumbai. Shri. Akash Rama Kondalkar, DI, CDSCO,WZ, Mumbai. Shri. Edlawar, DI, FDA, Thane.	For revalidation of COPP.	As Per Report	As Per Report	--	4th Quarter Annual inspection along with follow up of earlier inspection (If any)



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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
C	<u>HYDERABAD ZONE</u>							
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	13.10.2017 & 14.10.2017 Mr. Naveen Yadav, DI, CDSCO, Hyderabad and Mr. K.Anvesh, DI, DCA, Hyderabad along with subject expert Dr. A.S.Sreedhar, from CCMB, Hyderabad.	to verify the tenets of GMP as per Schedule M & WHO guideline requirements and adequacy of data for manufacturing of Trastuzumab (r-DNA origin - Bulk and drug product Trastuzumab 150mg/vial with 10mL bacteriostatic water for injection & 440mg/vial with 20mL bacteriostatic water for injection) in accordance with requirements of CDSCO guidance for industry	--	--	--	2 nd Quarter Annual inspection 3 rd Quarter Follow-up Inspection (if any)



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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, Trastuzumab Emtansine, Denosumab and Tenecteplase	17.08.2017 & 18.08.2017, Drugs Inspectors of CDSCO, Zonal Office, Hyderabad and DCA, TS along with the Expert form IIT Chennai	for grant of additional product license to manufacture for sale or for distribution of Recombinant DNA (r-DNA) derived drug Adalimumab in Form-28D	--	--	--	2nd Quarter Annual inspection 3rd Quarter Follow-up Inspection (if any)
3.	M/s. Shantha Biotechnics Limited, Sy. No. 274, Athvelli (V), Medchal (M), Hyderabad, TS.	Human Insulin	05.09.2014 & 06.09.2014, Drugs Inspectors of CDSCO, Zonal Office, Hyderabad and DCA, TS	for Grant of manufacturing permission of Insuman Basal & Insuman 25/75 (Human Insulin Suspension for Injection 40 IU/ml)	--	--	--	2nd Quarter Annual inspection 4th Quarter Follow-up Inspection (if any)



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4.	M/s. Bharat Biotech International Ltd., Genome Valley, Turkapally, Shameerpet (Mandal), Hyderabad-500078, T.S.	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 influenzae Type b Conjugate vaccine (Adsorbed), Recombinant Human Epidermal growth factor gel and SILVER SULFADIAZINE, CHLORHEXIDINE GLUCONATE AND RECOMBINANT HUMAN EPIDERMAL GROWTH FACTOR CREAM	24-09-2014, DDC(I), CDSCO, HYD, Drugs Inspectors of both DCA, TS and CDSCO, Hyderabad Zone & Drugs Inspectors from CDSCO, HQ, New Delhi	for grant of license for additional product Recombinant Human Epidermal Growth Factor Aqueous Bulk (rh-EGF) in Form 28 – D	--	--	--	2nd Quarter Annual inspection 4th Quarter Follow-up Inspection (if any)
5.	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	25-06-2012 & 16-10-2012, Drugs Inspectors of both DCA, TS and CDSCO, Hyderabad Zone along	for grant of additional products in Form 28D	--	--	--	3rd Quarter Annual inspection 4th Quarter Follow-up Inspection (if any)



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			with the Expert from CCMB					
9.	M/s. Gland Pharma Limited, Sy.No. 143-148, 150 & 151, Near Gandimaisam ma Cross Road, D.P Pally, Dundigal post, Outbullapur, Rangareddy, TS.	Human Insulin	20-01-2011 & 24-02-2011, Drugs Inspectors of both DCA, TS and CDSCO, Hyderabad Zone along with the Expert from CCMB	for grant of additional products in Form 28D	--	--	--	3 rd Quarter Annual inspection 4 th Quarter Follow-up Inspection (if any)



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D	AHEMABADABAD 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. Licence No. G/28D/BIO/02	1. Filgrastim Concentrated Solution (Bulk) 2. Pegylated Filgrastim Concentrated Solution (Bulk) 3. Interferon Alfa-2b Concentrated Solution 4. Pegylated Interferon alfa-2b (PegIFN alfa-2b) Concentrated Solution (Bulk) 5. Erythropoietin Concentrated Solution (Bulk) 6. Recombinant Human Parathyroid Hormone (Teriparatide) (Bulk) 7. Adalimumab (Bulk) 8. Trastuzumab (Bulk) 9. Bevacizumab (Bulk) 10. Follicle Stimulating Hormone Concentrated Solution (Bulk)	<u>30 to 31 January 2019</u> <u>FDCA,</u> <u>Gujarat:</u> Mr. Ashwin Radadiya, SDI <u>CDSCO</u> <u>Ahmedabad:</u> Mr. Parag Bhushan Gautam DI, Mr. Saurabh Garg DI	For grant of COPP as per WHO-GMP certification scheme.	Mentioned in Report.	Complied		3rd Quarter Annual inspection



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		11. Pegfilgrastim Injection in PFS and Vial (Injection) 12. Filgrastim Injection in PFS and Vial (Injection) 13. Interferon Alpha 2b injection in PFS and Vial (Injection) 14. Pegylated Interferon alfa-2b for injection in Lyo Vial (Injection) 15. Erythropoietin Injection In PFS and Lyo Vial (Injection) 16. Teriparatide Injection - Cartridge – 1 (Injection) 17. Adalimumab Injection – PFS (Injection) 18. Trastuzumab - Lyo- Vial (Injection) 19. Bevacizumab in Vial (Injection) 20. Follitropin alfa Injection in Cartridge (Injection)	<u>06/03/2019</u> <u>FDCA,</u> <u>Gujarat:</u> Mr. Arvind Zala, SDI Mr. L.R. Patel, DI <u>CDSCO</u> <u>Ahmedabad:</u> Mr. Rahul Panwar, DI	Investigation for voluntary recall of Filgrastim Injection 30 MIU	Mentioned in Report.	NA	Nil	
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)	<u>24 and 25</u> <u>May 2018</u> <u>FDCA,</u> <u>Gujarat:</u> Mr. Chinmay H. Patel, DI Mr. Mitesh	Grant of approval for change in the manufacturing facilities of Insulin drug product.	Mentioned in Report.	Complied	Nil	2 nd Quarter Annual inspection



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	Licence No. G/28D/10		Gangani, SDI <u>CDSCO Ahmedabad:</u> Mr. Saurabh Jain, DI					
3	M/s Cadila Pharmaceuticals Limited, 1389, Dholka, District, Ahmedabad, Gujarat State, India License no. G/28-D/11	1. Insulin Injection IP 40 IU 2. Isophane Insulin Injection IP IU 3. Biphasic Isophane Insulin Injection IP30/70 4. Recombinant Human Granulocyte Colony Stimulating Factor Injection (Filgrastim Injection) 5. Recombinant Human Erythropoietin injection IP 2000 IU-0.5 / 1 ml. 6. Recombinant Human Erythropoietin Injection IP 4000 IU- 1.0 ml	<u>06 to 07 September 2018</u> <u>FDCA, Gujarat:</u> Mr. Ashwin Radadiya, SDI <u>CDSCO Ahmedabad:</u> Mr. Saurabh Jain, DI	For revalidation of COPP under WHO-GMP Certification Scheme.	Mentioned in Report.	Complied	Nil	4th Quarter Annual inspection
4	M/s Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Balva	1. rHu GCSF 2. Peg rHu GCSF 3. rHu Interferon 4. rHu Erythropoietin	<u>26 to 27 September 2018</u> <u>FDCA,</u>	For Renewal of COPP as per WHO-GMP certification scheme		Complied	Nil	3rd Quarter Annual inspection



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	Highway, Moraiya, Tal-Sanand, Ahmedabad-382213, Gujarat, India License no. G/28D/BIO/01	5. rHu Folicle Stimulating Hormone 6. Peg Erythropoeitin 7. Ranibizumab 8. Bevacizumab 9. Rituximab 10. Etanercept 11. rHu Parathyroid Hormone 12. Denosumab 13. Trastuzumab 14. Romiplostim	Gujarat: Mr. Ashwin Radadiya, SDI CDSCO Ahmedabad: Mr. Rahul Panwar, DI Mr. R. Mohan, DI					
E	<u>Bangalore SubZone</u>							
1.	M/s. Biocon Limited, 20 th KM, Hosur Road, Electronics City, Bengaluru-560100	Insulin Human (rDNA Origin) Ph.Eur/USP – bulk Insulin Glargine (rDNA origin) – bulk Recombinant Human granulocyte colony stimulating Factor (Filgrastim) – bulk Pegfilgrastim (r-DNA origin) – Bulk Recombinant Streptokinase – Bulk	21.05.2018 to 22.05.2018 Mr. Mukesh kumar - Drugs inspector, CDSCO, Subzone, Bangalore Mr. Manohara K.V – Drugs	Revalidation COPP	--	--	--	2nd Quarter Annual Inspection 3rd Quarter follow up Inspection (If any)



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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 2019

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
			inspector, HQ, State Drugs control Karnataka					
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	Insulin Injection (rDNA Origin) Insulin Glargine Injection (rDNA Origin) Trastuzumab (r-DNA Origin) - bulk and its formulations Trastuzumab (PGS - bulk and formulations)-export purpose only Bevacizumab (r-DNA Origin) - bulk and its formulations Pegfilgrastim (r-DNA origin) formulations-export purpose only Recombinant Human Erythropoietin Injection Recombinant Streptokinase Injection Humanized Anti-EGFR Monoclonal Antibody (Nimotuzumab)-bulk and its formulations Itolizumab (T1hmAb) (r-DNA) - bulk and its formulations Itolizumab Injection	02.11.2018 Mrs. Anitha. A -Drugs inspector, CDSO, Subzone, Bangalore Mr. Manohara K.V – Drugs inspector, HQ, State Drugs control Karnataka	Revalidation COPP	--	--	--	2 nd Quarter Annual Inspection 3 rd Quarter follow up Inspection (If any)
3.	M/s Kemwell Biopharma Private limited , 34th KM, Tumkur Road,	Rituximab (r-DNA origin) 10ml vial, 10mg/ml	Inspection date:09.07.2018 Mr. Mukesh kumar -	For grant of manufacturing license in form 28D	--	--	--	2 nd Quarter Annual Inspection 3 rd Quarter follow up



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	T- Begur, Nelamangala, Bangalore – 562123, India		Drugs inspector, CDSCO, Subzone, Bangalore Mr. Dayanand Kadadevar – Drugs inspector, HQ, State Drugs control Karnataka					Inspection (If any)
4.	M/s. MYLAN LABORATORI ES 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	Inspection Date: 20/10/2016 and 21/10/2016 Inspection Team: Mr. V.S. Prabhakar, DI, CDSCO, Subzone Bangalore K.V.	Grant of license in Form 28D (No. KTK/28D/19/2017) Date of issue: 12/05/2017	--	--	--	2nd Quarter Annual Inspection 4th Quarter follow up Inspection (If any)



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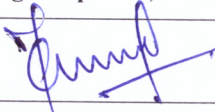
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Central Inspection Plan Using Risk Based Approach of r-DNA products Manufacturing Units for 2019

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			Manohara, DI, HQ, SLA Dr. KV. Ramana, Subject Expert, Scientist, Defense Food Research Lab, Mysuru.					

Note:

- 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.

Prepared By		Reviewed by		Approved By	
Name	Sachinkumar Kapse	Name	Mukesh Kumar	Name	Mrs. Swati Srivastava
Designation	Drugs Inspector, CDSCO (HQ)	Designation	Drugs Inspector, CDSCO (HQ)	Designation	Deputy Drugs Controller (India), CDSCO (HQ)
Sign		Sign		Sign	