F.No: QA/02/Central Inspection Plan/CT/rDNA/2018
Director General of Health Services
Central Drugs Standard Control Organisation
Office of Drugs Controller General (India)
FDA Bhawan, Kotla Road,
New Delhi-110002
(QA Division)

Dated: 17 JAN 2018

Office Memorandum

As a process of Clinical trial oversight, CDSCO-HQ has prepared tentative Central Inspection Plan for the Year 2018 for inspections of the clinical trials permitted with respect to r-DNA products in accordance with the elements of SOP QA-INS-004. You are requested to conduct clinical trial inspections as per plan with the team comprising of inspectors trained in GCP, along with subject expert and an officer from CDSCO-HQ. Drugs inspectors from respective states may also join the inspection team.

The concerned CDSCO Zonal officers are also requested to confirm the status of clinical trial site before planning the inspection at respective site. The clinical trial inspection report shall be submitted after completion of inspection to this office along with your recommendations for further action by this office.

(Dr. G. N. Singh)
Drugs Controller General (India)

Encl: 1. Central Inspection Plan for clinical trial inspections for year 2018 for r-DNA products

To:
All DDC(I)s of North Zone, West Zone, South Zone, East Zone, Ahmedabad Zone, Hyderabad Zone, Varanasi Sub Zone, Jammu Sub Zone, Bangalore Sub zone and Baddi Sub Zone.

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List of Clinical Trials (rDNA Products) to be inspected in the year 2018

Sr. No.	Name of Investigational Product	Study Title
1	Trastuzumab	Prospective, Multicenter, Randomized, Double-blind, Parallel group Study to Compare the Efficacy and Safety of GBR 200 (similar biologic of Trastuzumab) versus Innovator Trastuzumab both when Given in Combination with Paclitaxel in Patients Diagnosed with HER2 Positive Metastatic Breast Cancer.
2	Premixed human insulin biphasic injectable suspension	A Prospective, multicenter, randomized, parallel group, active controlled, Phase III study to compare the efficacy, safety and Immunogenicity of Premixed Human Insulin Biphasic (30%Human Insulin Soluble Injection and 70% Human Insulin Isophane Suspension) Injectable Suspension of MJ Biopharm Private Ltd with Huminsulin 30/70 in treatment of patients with type 2 Diabetes Mellitus.
3	Regen-D (recombinant epidermal growth factor)	A Phase II randomized double blind placebo controlled study to assess safety and efficacy of REGEN-D in treatment of cracked feet.
4	Denosumab	A Prospective, multicenter, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045(Denosumab)/Xgeva for prevention of skeletal related events in patients with bone metastases from solid tumors
5	Rabimabs	Randomized, multi-centric, open-label, comparator-controlled study to evaluate the efficacy and safety of RABIMABS administered in conjunction with Vaxirab N for post-exposure prophylaxis inpatients following potential Rabies exposure.
6	R-TPR-045 (Denosumab)	Prospective, multi-centre, randomized, double blinded, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045/Prolia® in post-menopausal woman with osteoporosis.
7	Ranicizumab	Prospective, multi-centre, randomized, double blind, two-arm, parallel group, active control, comparative clinical trial to evaluate efficacy and safety of R-TPR-024/Lucentis® in patients with neovascular (wet) age related macular degeneration.
8	Romiplostim	**1.** Single dose Pharmacokinetic and Pharmacodynamic study of inj. Romiplostim from Intas Pharmaceutical Ltd. and inj. Romiplostim of Amgen Inc. (US licenced) in patients with chronic refractory immune (Idiopathic) thrombocytopenic purpura. **2.** Immunogenicity study to evaluate the efficacy and safety of inj. Romiplostim from Intas Pharmaceutical Ltd. in adult

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		patients with chronic refractory immune (Idiopathic) thrombocytopenic purpura.
9	Soluble insulin injection R 40 IU/mL	A randomized, double blind, balanced, two treatment, two period, two sequence, single dose, crossover, pharmacokinetic and pharmacodynamics bioequivalence study of soluble insulin injection R 40 IU/mL of Unichem Laboratories Ltd., India with Huminised R 40 IU/mL of Eli Lilly and Company (India) Pvt. Ltd in Healthy Adult Male Human Subjects using Euglycemic Clamp technique under fasting conditions
10	Biphasic Insulin Aspart Injection (30/70)	Pilot Phase-I study to compare Pharmacokinetics and Pharmacodynamic between Wockhardt's Biphasic Insulin Aspart Injection (30/70) and Novomix® 30, in healthy male subject.
11	Aflibercept	Structured Post Marketing Surveillance study on Aflibercept Intravitreal Injection (Eylea)
12	r-hMG (Recombinant human Menopausal Gonadotrophin)	Phase-III clinical study to compare the efficacy and safety of r-hMG (Recombinant human Menopausal Gonadotrophin) and HP-hMG in subject undergoing controlled ovarian stimulation for ART Disease of new born.
13	Cnsegna- 30/70 (Biphasic isophane insulin 30/70 injection 200 IU) and Mixard 30/70 (100 IU)	A randomized, single centre, double blind, two treatment, two period, crossover, glucose clamp study to test for bioequvalnce between wockhartd's Cnsegna- 30/70 (Biphasic isophane insulin 30/70 injection 200 IU) and Mixard 30/70 (100 IU) in Healthy subject.
14	Trastuzumab Emtansine (Hetero)	A Randomized, multi-dose, Multi-Center, comparative, parallel study to evaluate the Efficacy, Safety and pharmacokinetic Chrectersticks of intravenous infusion of Trastuzumab Emtansine (Hetero) and Reference Medicinal Product (trastuzumab Emtansine, roche) inpatients of HER2-positive metastatic breast cancer (TREMBC study).
15	Trastuzumab	A Randomized, multi-dose, Multi-Center, comparative, parallel study to evaluate the Efficacy, Safety and pharmacokinetic Charectersticks of intravenous infusion of Trastuzumab (Hetero) and Reference Medicinal Product (trastuzumab, Genentech, Inc.) in combination with standard chemotherapy in patients of HER2-positive metastatic breast cancer (TRUMAB study).
16	INFIMAB® (Infliximab)	Phase IV study to evaluate safety and efficacy of INFIMAB® (Infliximab) in patients with moderate to severe Crohn's disease.
17	Turoctocog alfa (Human Coagulation Factor VIII; r-DNA origin)	Phase IV study of Turoctocog alfa (Human Coagulation Factor VIII; r-DNA origin)
18	WCK 9444 with	A trial to compare the pharmacodynamic and pharmacokinetic

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	MIXTARD® 30/70	properties of Wockhardt's WCK 9444 with MIXTARD® 30/70 and simultaneous injections of LANTUS® and ACTRAPID® in healthy subjects.
19	Recombinant Human Insulin 40 IU/mL (BioGenomics Limited)	A Phase-I, Double-blind, Randomized, Single-dose, Two-period, Two-Sequence, Cross-over Euglycemic Insulin Clamp Study To Demonstrate Equivalence In The Pharmacokinetics and Pharmacodynamic Properties of Recombinant Human Insulin 40 IU/mL (BioGenomics Limited) and Huminsulin® R 40 IU/mL and To Assess The Safety and Tolerability In Healthy, Adult, Human Male Subjects Under Fasting Conditions" for the drug product recombinant human insulin 40 IU/ML.
20	Insulin Tregopil (IN-105)	An open label, Multi center,Randomized, Parallel group Phase II/III clinical study to evaluate the Efficacy and safety of Insulin Tregopil (IN-105) compared with Insulin Aspart in the treatment of Patients with Type 2 Diabetes Mellitus on stable dose of Metformin and insulin Glargine.
21	Biphasic Isophane Insulin Injections (Wockhardt's Wosulin 30/70) and Actraphane 30	A randomized, single centre, double-blind, two-treatment, two-period, crossover glucose clamp study to test for bioequivalence between Biphasic Isophane Insulin Injections (Wockhardt's Wosulin 30/70) and Actraphane 30, in healthy subjects.
22	Filgrastim	A randomized, controlled, comparative, open-label, multicenter study on the safety and efficacy of Neutrogen (Filgrastim manufactured by M/s Virchow Biotech) and Neupogen (Filgrastim manufactured by M/s Roche) in prevention of chemotherapy-induced neutropenia.
23	Pegfilgrastim	A randomized, controlled, comparative, open-label, multicenter study on the safety and efficacy of PEG-Neutrogen (Pegfilgrastim manufactured by M/s Virchow Biotech) and Neulastim (Pegfilgrastim manufactured by M/s Roche) in prevention of chemotherapy-induced neutropenia.
24	pegfilgrastim Injection PFS 6mg/0.6ml	An assessor-blind, balanced, randomized, two-treatment, two-period, single-dose, two-way, crossover, comparative, pharmacokinetic and pharmacodynamic study of subcutaneous injection of INTP5 (pegfilgrastim Injection PFS 6mg/0.6ml) of Intas Pharmaceutical Ltd., India against Neulasta (pegfilgrastim Injection PFS 6mg/0.6ml) of Amgen Inc., USA in Healthy, adult human subjects under fasting.
25	Bevacizumab	A Phase IV Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero-Bevacizumab in solid malignancies.
26	Rituximab	A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero-Rituximab.
27	Bevacizumab	An open label, single arm, multicentric, Phase IV study to evaluate the safety and efficacy of Bevacizumab of Intas Pharmaceuticals Ltd in approved indications.