Clinical trial permission 2020						
Sr.No.	**Firm Name**	**Drug Name**	**Permission date**	**Permission No.**	**Phase of study**	**Trial title**
1	Enzene Biosciences Limited	Bevacizumab Injection 100 mg/4 mL	7-Jan-2020	BIO/CT/19/000052	Phase III	A prospective, multicenter, randomized, double blind, Phase III study to compare the efficacy and safety of Biosimilar Bevacizumab of Enzene Biosciences Ltd. versus Innovator Bevacizumab both in Combination with CAPEOX in Patients with Metastatic Colorectal Cancer Protocol No: ALK19/ENZ137-BEV1
2	Levim Biotech LLP	Liraglutide injection (r-DNA)	7-Jan-2020	BIO/CT/19/000022	Phase I (PK-PD)	An open label, balanced, randomized, two treatment, two period, two way crossover study to compare the single & multiple dose (steady state) pharmacokinetics profile of biosimilar Liraglutide injection with Victoza in healthy adult, human subjects vide Protocol No. 123-19
3	GlaxoSmithKline Pharmaceuticals Limited	Mepolizumab Powder for Solution for Injection	15-Jan-2020	BIO/CT/19/000014	Phase IV	A Phase 4, open label, single arm, 24-week, phase 4 study to evaluate the safety and efficacy of Mepolizumab 100mg SC administered every 4 weeks in Indian participants aged ≥ 18 years with severe eosinophilic asthma requiring oral corticosteroid treatment to maintain asthma control (PRISM), Protocol No. 209682 (Amendment 01)
4	Intas Pharmaceuticals Limited	Granulocyte Colony Stimulating Factor (Filgrastim)	24-Jan-2020	BIO/CT/19/000083	Phase I (PK-PD)	“A Randomized, Assessor-Blind, Multiple-Dose, Two-Treatment, Two-Period, Two-Way Crossover Study Comparing The Pharmacodynamics of INTP1 From Intas Pharmaceuticals Ltd., India And Neupogen of Amgen Inc., USA following Subcutaneous Injections In Healthy, Adult Human Subjects vide Protocol No: 0365-19
5	Reliance Life Sciences Pvt Ltd	Ramucirumab Injection	30-Jan-2020	BIO/CT/19/000055	Phase III	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-069 / Cyramza® in patients with non-small cell lung cancer vide Protocol No.: RLS/ONC/2019/02
6	Eris Lifesciences Limited	Recombinant Human Thrombopoietin Injection	4-Feb-2020	BIO/CT/19/000101	Phase III	A Phase III,Randomized, Open-Label, Multicentre, Clinical Trial to evaluate the efficacy and safety of Recombinant Human Thrombopoietin (rhTPO) Injection compared with Romiplostim injection in Indian Patients with Immune Thrombocytopenia. Protocol No.CT-TPIAO-001-ITP-2019
7	M.J.Biopharm Pvt.Ltd	Insulin Injection, Biphasic Isophane IP /Ph. Eur. 100 IU/ml in 3 ml cartridge (containing 30 % human insulin soluble injection and 70 % human insulin isophane suspension)	7-Feb-2020	BIO/CT/19/000094	Phase IV	A Prospective, Multi-center, Phase IV Study to Assess the Safety, Efficacy and Immunogenicity of BIOSULIN® 30:70 (Insulin Injection, Biphasic Isophane 100 IU/ml of M.J.Biopharm Private Limited) in Treatment of Patients Diagnosed with Type 2 Diabetes Mellitus”, vide Protocol No.: PHIB/MJBPL/PHASE IV/2019

8	Accutest Research Laboratories (I) Pvt. Ltd	Recombinant Growth Hormone (ALT-P1)	21-Feb-2020	BIO/CT/19/000028	Phase I	A Randomised, Open-labelled, Active-controlled, Single and Multiple Dose, Dose Escalating, Sequential Dose Group, Parallel Trial Investigating Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Once weekly long-acting Recombinant Growth Hormone (ALT-P1) Compared to Once daily growth hormone (Norditropin) in Healthy Subjects, vide Protocol No.: ARL/19/044
9	Enzene Biosciences Ltd	Adalimumab (40 mg/0.8 mL) Pre-filled syringe	25-Feb-2020	BIO/CT/19/000087	Phase III	A prospective, multicenter, randomized, double blind, Phase III study to compare the efficacy and safety of Biosimilar Adalimumab injection of Enzene Biosciences Ltd. with HUMIRA® (adalimumab) injection in subjects with active Ankylosing spondylitis (AS), Protocol Number –ALK20/ENZ129-ADA1
10	Dr. Reddys Laboratories Limited	Bevacizumab (r-DNA origin) drug product 100mg/4ml & 400mg/16 m	2-Mar-2020	BIO/CT/19/000082	Phase IV	A Prospective, Multi-centre, Phase IV study to evaluate Safety and Efficacy of Dr. Reddy's Bevacizumab (DRL_BZ) in patients with Solid Tumors vide Protocol No.: BZ-02-001,
11	Wockhardt Limited	Biphasic Isophane Insulin Injection 100 IU/mL	30-Mar-2020	BIO/CT/20/000014	Phase I (PK-PD)	A Randomized, Single Center, 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 Vide Protocol No. WWOS(M)-106
12	Biocon Biologics India Limited	Itolizumab Injection	9-Apr-2020	BIO/CT/20/000037	Phase - II	A Multi-Centric, Open label, Two Arm Randomized, Pivotal Phase - II Trial to Study the Efficacy and Safety of Itolizumab in COVID-19 Complications, vide Protocol No.: ITOLI-C19-02-I-00
13	JSS Medical Research India Pvt. Ltd	Tocilizumab	8-May-2020	BIO/CT/20/0000051	Phase III	A Multi-center, Randomized Controlled, Phase III Study to evaluate the Clinical Outcomes and Safety of Tocilizumab along with Standard of Care in Patients with Cytokine Release Syndrome associated with COVID-19 infection, Protocol Number – Protocol Number: TCZ/ COVID-19/01/2020
14	Cadila Healthcare Limited	Pegylated interferon alfa-2b	11-May-2020	BIO/CT/20/000057	Phase II	A phase II, randomized, controlled, open-label study to evaluate the efficacy and safety of Pegylated IFN alfa-2b in the treatment of adult patients diagnosed with SARS-Co V2 (COVID-19)", vide Protocol No.: PEGI.20.002
15	Dr. Reddy's Laboratories Limited	Tocilizumab concentrate for solution for IV infusion	15-Jun-2020	BIO/CT/19/000047	Phase I (PK-PD)	A Phase I, Double Blind, Randomized, Parallel-group, Single dose, Three arm, Comparative Pharmacokinetic and Pharmacodynamic Study of Dr. Reddy's Tocilizumab (DRL_TC), USA sourced Reference Tocilizumab (Actemra®) and EU sourced Reference Tocilizumab (RoActemra®) Administered by the Intravenous Route to Normal Healthy Male Volunteers, vide Protocol No.: TC-01-001
16	Cipla Limited	Insulin Human 4 units, 8 units and 12 units single-use cartridge Inhalation Powder (Recombinant human insulin)	25-Jun-2020	BIO/CT/19/000076	Phase III	Randomized, Double-blind, Placebo-controlled, Multicenter, Phase 3 Clinical Trial to Evaluate the Efficacy and Safety of Prandial Technosphere® Insulin Inhalation Powder Versus Placebo Inhalation Powder in Patients with Type 2 Diabetes Mellitus Inadequately Controlled with Oral Antidiabetic Drugs Over a 24-week Treatment Period, vide Protocol No.: CP/01/19

17	Intas Pharmaceuticals Limited	Ranibizumab Injection	30-Jun-2020	BIO/CT/20/000008	Phase III	A Double Masked, Parallel Group, Randomized, Multicenter, Clinical Study to Compare Efficacy and Safety of Intas Ranibizumab with Lucentis® in Patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD) vide Protocol No.: 0504-19
18	Genesys Biologics Pvt. Ltd	Insulin Glargine Injection 100IU/ml	3-Jul-2020	BIO/CT/19/000035	Phase I (PK/PD)	An open label, randomized, two-treatment, two-sequence, four-period, single-dose, full replicate crossover bioequivalence study of GEN1501 (Insulin Glargine Injection) 100 U/ml of GeneSys Biologics Pvt. Ltd. Hyderabad, India and LANTUS® (Insulin Glargine Injection) 100 U/mL of Sanofi-Aventis, in healthy male, adult, human subjects under fasting conditions vide Protocol No. 19-056
19	Cipla Limited	Tocilizumab Injection [180mg/mL Prefilled Syringes (162mg/0.9mL)]	3-Jul-2020	BIO/CT/20/000003	Phase IV	Phase IV, open label, non-comparative, multicentre study to evaluate safety and efficacy of subcutaneous Tocilizumab in subjects with giant cell arteritis (GCA) vide Protocol Study Code: CP/07/19
20	BioGenomics Limited	Insulin Glargine 100 U/mL	10-Jul-2020	BIO/CT/20/000021	Phase I (PK-PD)	A double-blind, randomized, single-center, two treatment, four period, two sequence, replicate crossover, euglycemic clamp study to demonstrate equivalence in the pharmacokinetic and pharmacodynamic properties of Insulin Glargine 100 U/mL of BioGenomics Limited and Lantus@ (Insulin Glargine 100 U/mL of Sanofi-Aventis) in healthy, adult, human male subjects under fasting condition vide Protocol No.: 20-VIN-0108
21	M.J.Biopharm Pvt. Ltd	Insulin Glargine Injection 100IU/ml	10-Jul-2020	BIO/CT/20/000002	Phase I (PK/PD)	A double-blind, randomized, single-center, balanced, two sequence, four-period, two treatment, fully replicate, crossover, euglycemic clamp study to compare the pharmacokinetic and pharmacodynamic activity of Insulin Glargine 100 units/ml of M.J. Biopharm private limited with Lantus® (Insulin Glargine injection) 100 units/ml of Sanofi Aventis in healthy adult human subjects under fasting condition vide Protocol No.: MJBPL-RIG01
22	Stelis Biopharma Private Limited	Insulin Glargine 100 U/mL	10-Jul-2020	BIO/CT/19/000090	Phase I (PK-PD)	A double-blind, randomized, single-center, two treatment, four period, two sequence, replicate crossover, euglycemic clamp study to demonstrate equivalence in the pharmacokinetic and pharmacodynamic properties of Insulin Glargine injection 100 IU/mL of Stelis Biopharma and LANTUS® (Insulin Glargine injection 100 IU/mL of Sanofi Aventis) in healthy, adult, human subjects under fasting condition", vide Protocol Number/ Project No. : 19-VIN-0348
23	BioGenomics Limited	Insulin aspart Mix 30	10-Jul-2020	BIO/CT/20/000027	Phase I (PK/PD)	A Randomized, Double Blind, Single Center, Two Treatment, Two-Period, Two Sequence, Crossover, Euglycemic clamp study to demonstrate equivalence in the Pharmacokinetic and Pharmacodynamic properties of Insulin Aspart Mix 30 of BioGenomics Limited and NovoMix®30 of Novo Nordisk in healthy, adult, human male subjects under fasting condition" vide Clinical Trial Protocol No. 20-VIN-0109,

24	AstraZeneca Pharma India Limited	Druvalumab	13-Jul-2020	BIO/CT/19/000108	Phase IV	A prospective, multicenter, Phase-IV clinical trial to assess safety of Durvalumab in Indian adult patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) and urothelial cancer. Study Code - D133HC00003
25	Cadila Healthcare Limited	Adalimumab (40 mg/0.8 mL) Pre-filled syringe	28-Jul-2020	BIO/CT/20/000091	Phase II	A phase II, randomized, controlled, open-label study to evaluate the efficacy and safety of adalimumab in the treatment of adult patients diagnosed with SARS-CoV2 (COVID-19) vide Protocol Number: ADAL 20 001
26	Baxalta Bioscience India Pvt.ltd	Coagulation Factor VIII (Recombinant) rFVIII, Plasma/ Albumin Free Method; Octocog Alfa	19-Aug-2020	BIO/CT/20/000017	Phase IV	Phase 4, Multicenter, Prospective, Interventional, Post-Marketing Study in Hemophilia A Patients in India Receiving ADVATE as On-Demand or Prophylaxis Under Standard Clinical Practice", vide Protocol Number: TAK-761-4009
27	Sun Pharmaceutical Industries Limited	Ranibizumab Solution for Injection 10 mg/ml, 0.23 ml vial	21-Aug-2020	BIO/CT/20/000087	Phase III	A Phase III, Comparative, Double Blind, Randomized, Multi-centric study to compare the Efficacy, Safety and Immunogenicity of Sun's Ranibizumab with Reference Biologic in Patients with Neovascular Age-related Macular degeneration (wet AMD).", vide Protocol Number: Protocol No. ICR/19/009
28	Biocon Biologics India Limited	Itolizumab Injection	25-Aug-2020	BIO/CT/20/000093	Phase IV	A multicentre, single arm, Phase IV clinical trial to evaluate the safety and efficacy of Itolizumab for the treatment of cytokine release syndrome (CRS) in moderate to severe acute respiratory distress syndrome (ARDS) patients due to COVID 19, vide Protocol No.: ITOLI-C19-04-I-01
29	Bristol-Myers Squibb India Pvt. Ltd	Ipilimumab (r-DNA origin) Injection, 50 mg/10 mL (5 mg/mL)	17-Sep-2020	BIO/CT/20/000058	Phase III	A Phase 4 Study of Nivolumab in Combination with Ipilimumab in Patients with Previously Untreated Advanced Renal Cell Carcinoma and Intermediate- or Poor-risk Factors conducted in India as per Protocol No.: CA209-7C9
30	Intas Pharmaceuticals Limited	Teriparatide solution for injection prefilled pen 20 micrograms/ 80 microliters, subcutaneous injection	25-Sep-2020	BIO/CT/20/000089	Phase I (PK-PD)	An Assessor-Blind, Randomized, Three-Treatment, Three-Period Single-Dose, Crossover, Bioequivalence Study of INTG8 of Intas Pharmaceuticals Limited, India to Forsteo® (Eli Lilly Nederland B.V., The Netherlands) and Forteo® (Lilly USA, LLC) in Healthy Men and Postmenopausal Women after Subcutaneous Administration vide Protocol Project No.:0258-20
31	Intas Pharmaceuticals Limited	Teriparatide solution for injection prefilled pen 20 micrograms/ 80 microliters, subcutaneous injection	5-Oct-2020	BIO/CT/19/000097	Phase III	A randomized, assessor-blind, multicenter, parallel arm study comparing immunogenicity potential of Teriparatide of Inta Pharmaceutical Limited with Forteo in postmenopausal women with osteoporosis, vide Protocol No.: 0633-19

32	Intas Pharmaceuticals Limited	Denosumab 60 mg Solution for Injection	8-Oct-2020	BIO/CT/20/000062	Phase III	A Randomized, Double-Blind, Active-Controlled, Parallel Arm, Multicenter Study Comparing Pharmacokinetics, Pharmacodynamics, and Immunogenicity of Denosumab of Intas Pharmaceutical Limited (60 mg/mL) with Prolia® in Postmenopausal Women with Osteoporosis vide Protocol No. 0774-19 for export purpose only
33	Reliance Life Sciences Pvt. Ltd	Omalizumab for Injection	9-Oct-2020	BIO/CT/20/000076	Phase IV	Prospective, multi-center, open-label, single-arm, clinical study to evaluate safety and efficacy of OmaliRel™ in patients with moderate to severe persistent asthma vide Protocol No.: RLS/RES/2020/02
34	Reliance Life Sciences Pvt. Ltd	Ranibizumab Injection	19-Oct-2020	BIO/CT/20/000126	Phase IV	A prospective, multi-center, single arm, open label, study to evaluate safety and efficacy of RanizuRelTM containing Ranibizumab for intra-vitreal injection, manufactured by Reliance Life Sciences, Pvt. Ltd. India in patients with neovascular (wet) age-related macular degeneration vide Protocol No.: RLS/OPT/2020/03