

CT NOC from Jan to Dec 2019

Sl.No.	Firm Name	Drug Name	Permission No.	Date of Issue	Protocol	Version and date	Phase
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 (India) - 400701	Panitumumab	BIO/CT/18/000055	11-Jan-19	Phase 3 clinical trial titled "Prospective, multicenter, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of Panitumumab (R-TPR-048) / Vectibix in patients with metastatic colorectal cancer	Protocol No. RLS/ONC/2018/01, version 2.0, dated 11 Dec 2018	Phase III
2	M/s Ferring Pharmaceuticals Pvt. Ltd. ,The Capital, 509/510, A Wing, 5th Floor Bandra-Kurla Complex, Bandra (East) Mumbai (India) - 400051	Follitropin delta	BIO/CT/18/000070	02-Feb-19	Phase 3 clinical trial titled "A randomised, controlled, assessor-blind, parallel groups, multicentre trial in India comparing the efficacy and safety of FE 999049 (follitropin delta) with follitropin alfa (GONAL-F) in controlled ovarian stimulation in women undergoing an assisted reproductive technology programme	Protocol No.: 000320; Version 1.0 dated: 12 Jun 2018	Phase III
3	M/s Reliance Life Sciences Pvt Ltd ,Dhirubhai Ambani Life Sciences Center, R-282 TTC Area Of MIDC, Thane -Belapur Road, Rabale Navi Mumbai (India) - 400701	Natalizumab	BIO/CT/18/000064	04-Feb-19	Phase III clinical trial titled "Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-047 / Tysabri in patients with relapsing multiple sclerosis	Protocol No.: RLS/MS/2018/02; Version 2.0, Dated: 11 Dec 2018	Phase III
4	M/s. Lupin Limited, Kalpataru Inspire, 3rd Floor, off Western Express Highway, Santacruz (East), Mumbai, Maharashtra (India) – 400055	Etanercept	BIO/CT/18/000095	08-Mar-19	Phase 4 clinical trial titled "Phase IV, Multicentre, Clinical Study to Assess the Safety of Lupin Etanercept in Real World Clinical Setting	Protocol No.: LRP/Lupin Etanercept/2018/002; Version 1.0, Dated: 17 Feb 2019	Phase IV
5	M/s. Cliantha Research Limited ,Opposite Pushparaj Towers Nr. Judges Bungalows, Bodakdev, Ahmedabad (India) - 380054	Trastuzumab) powder for concentrate for solution for intravenous infusion	BIO/CT/18/000068	13-Mar-19	Bioequivalence Study entitled "A randomized, double-blind, parallel, single dose comparative pharmacokinetic study of AryoTrust (Trastuzumab) powder for concentrate for solution for intravenous infusion and 'HERCEPTIN' (Trastuzumab) powder for concentrate for solution for intravenous infusion in healthy, adult, male subjects"	Protocol No. BA18659410, Version No. 00, dated 14.08.2018	BA-BE
6	M/s Wockhardt Limited, Research Centre, MIDC, D-4, MIDC, Chikalthana, Aurangabad Maharashtra (India) - 431006	Biphasic isophane insulin	BIO/CT/18/000088	10-Apr-19	Phase 1 clinical trial titled "A pilot study to compare bioavailability between Biphasic isophane insulin injections wockhardt's Wosulin® 30/70 and Humulin 70/30, in healthy male subjects" as per Protocol no. W-WOS(M)-108 Version 01, dated 31-Aug-2018 for export purpose	Protocol no. W-WOS(M)-108 Version 01, dated 31-Aug-2018	Phase I

7	M/s. Intas Pharmaceuticals Limited, Plot No. 423/P/A, Sarkhej-Bavla Highway, Moraiya, Tal: Sanand, Ahmedabad – 382213, Gujarat, India	Trastuzumab	BIO/CT/19/000008	29-Apr-19	Phase 4 clinical study entitled "A multicentric, open label, single arm study to evaluate the safety and efficacy of INTP26 (trastuzumab biosimilar) in patients with HER2-overexpressing breast (early or metastatic) cancer or metastatic gastric"	Protocol No.: 0566-18, Version No. 1.0, Protocol Date 10-AUG-2018,	Phase IV
8	M/s Enzene Biosciences Limited Plot No. 165/1/26, T- Block MIDC, Bhosari, Pune Pimpri Chinchwad, Maharashtra (India) - 411026	Cetuximab	BIO/CT/18/000065	03-May-19	Phase 3 clinical trial titled "A prospective, multicentre, randomized, double blind, parallel group study to compare the efficacy and safety of biosimilar Cetuximab versus innovator Cetuximab in combination with platinum-based chemotherapy in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)	Protocol No.: ALK18/ENZ124-CET1; Version No: 02 Date: 27-Mar-2019	Phase III
9	M/s Serum Institute of India Pvt. Ltd., 212/2, off. Soli Poonawalla Road Hadapsar Pune (India) - 411028	Rabies Human Monoclonal Antibody	BIO/CT/18/000091	30-May-19	Phase IV clinical trial of the new drug Rabies Human Monoclonal Antibody	Protocol No.: Rab-04 Version No. 2.0 Protocol Date 14-SEP-2018	Phase IV
10	M/s Wockhardt Limited, Research Centre, MIDC, D-4, MIDC, Chikalthana, Aurangabad Maharashtra (India) - 431006	Isophane Insulin	BIO/CT/18/000090	01-Jul-19	Phase 1 clinical trial titled "A Pilot Study To Compare Bioavailability Between Recombinant Human Isophane Insulin Injections Wockhardt's Wosulin® N and Humulin® N, In Healthy Male Subjects	Protocol No.: W-WOS(N)-103 V. No.03, dated 08-May-2019	Phase I
11	M/s Wockhardt Limited, Research Centre, MIDC, D4, Chikalthana, Aurangabad-431006, Maharashtra, India	Biphasic Isophane Insulin	BIO/CT/18/000089	02-Jul-19	PK/PD Study entitled "A Pilot study to compare Bioavailability between Biphasic Isophane Insulin Injections Wockhardt's Wosulin 30/70 and Actraphane 30 in healthy Male subjects", Protocol No. W-WOS(M)-107; Version No. 02; date 30 April 2019 for Export purpose	Protocol No.: W-WOS(M)-107, Version No. 02, Protocol Date 30-APR-2019,	PK-PD
12	M/s Reliance Life Sciences Pvt Ltd ,Dhirubhai Ambani Life Sciences Center, R-282 TTC Area Of MIDC, Thane -Belapur Road, Rabale Navi Mumbai (India)	Golimumab	BIO/CT/19/000009	02-Jul-19	Phase III clinical trial of the new drug Golimumab Solution for Injection to compare the efficacy, pharmacokinetics, pharmacodynamics, safety and immunogenicity of R-TPR-044 / Simponi® in patients with moderately to severely active rheumatoid arthritis on a stable dose of methotrexate as per	Protocol No.: RLS/RA/2018/05 Version 2.0, Dated 15 May 2019	Phase III
13	M/s Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center, R-282, TTC Area Of MIDC, Thane -Belapur Road, Rabale Navi Mumbai (India) - 400701	Tenecteplase	BIO/CT/19/000021	12-Jul-19	Phase IV Study entitled "A prospective, multi-centre, phase IV study to evaluate safety and efficacy of TenecteRel (Tenecteplase manufactured by Reliance Life Sciences Pvt. Ltd.)", Protocol No. RLS/PMS/2017/01; Version 2.0, Dated: 24 Jun 2019	Protocol No.: RLS/PMS/2017/01; Version 2.0, Dated: 24 Jun 2019	Phase IV

14	M/s Pfizer Products India Private Limited , The Capital 1802/1901 Plot No. C-70 G Block Bandra Kurla Complex BandraEast Mumbai City (India) - 400051	Nonacog Alfa (recombinant coagulation factor IX	BIO/CT/19/000031	12-Jul-19	A single country, multicenter, open-label and non-randomized pragmatic trial with nonacog alfa prophylaxis and treatment of bleeding episodes in previously treated patients with moderately-severe to severe hemophilia B for a duration of 8 weeks	Protocol No.: B1821059, Version Date 10.04.2019	Phase IV
15	M/s Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center, R-282, TTC Area Of MIDC, Thane - Belapur Road, Rabale Navi Mumbai (India) - 400701	Ustekinumab	BIO/CT/19/000001	13-Aug-19	Phase 3 clinical trial entitled "Prospective, multicenter, randomized, double-blind, two arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of Ustekinumab (R-TPR-046)/Stelara® in patients with moderate to severe plaque psoriasis"	Protocol No.: RLS/DRM/2018/04; Version 2.0, Dated: 26-Jul-2019	Phase III
16	M/s. Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center, R-282, TTC Area Of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai (India) - 400701	Recombinant Human Growth Hormone (Somatropin) Injection	BIO/CT/19/000026	30-Aug-19	Phase IV clinical trial entitled "A prospective, multicentre, phase IV study to evaluate safety and efficacy of SomatoRel (recombinant human growth hormone manufactured by Reliance Life Sciences Pvt. Ltd.) in growth hormone deficient children"	Protocol No.: RLS/PMS/2019/03; Version 2.0, Dated 02 Aug 2019	Phase IV
17	M/s. Lupin Limited (Biotechnology Division), Gat No: 1156, Village - Ghotawade, Taluka - Mulshi, Pune – 412115 Maharashtra, India	Recombinant Pegylated Granulocyte Colony Stimulating Factor (Pegfilgrastim, 6mg/0.6 ml solution)	BIO/CT/19/000072	27-Sep-19	Phase I PK-PD clinical trial entitled "A Double-Blind, Balanced, Randomized, Single-Dose, Two-Treatment, TwoSequence, Two-Period Crossover Comparative PharmacokineticsPharmacodynamics (PK-PD)Study of Lupin's Pegfilgrastim 6mg/0.6ml subcutaneous injection manufactured by Lupin Limited, India and Neulasta (Pegfilgrastim 6mg/0.6ml) subcutaneous injection manufactured by Amgen Inc. US administered in Healthy, Adult, Human Subjects	Protocol No.: ARL/18/360; Amendment Version No. 02, dated 31 May 2019	Phase I PK-PD
18	M/s. Reliance Life Sciences Pvt. Ltd., Dhirubhai Ambani Life Sciences Center, R-282, TTC Area Of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai (India) - 400701	Etanercept Injection	BIO/CT/19/000025	27-Sep-19	Phase IV clinical trial entitled "Application for grant of permission to conduct Phase IV clinical study entitled "A prospective, multi-centre, phase IV study to evaluate safety and efficacy of EtanerRel (Etanercept manufactured by Reliance Life Sciences Pvt. Ltd.), Protocol No.: RLS/PMS/2018/03; Version 2.0, dated: 01 Aug 2019	Protocol No.: RLS/PMS/2018/03; Version 2.0, dated: 01 Aug 2019	Phase IV
20	M/s Reliance Life Sciences Pvt Ltd., Dhirubhai Ambani Life Sciences Center, R-282 TTC Area Of MIDC, Thane -Belapur Road, Rabale Navi Mumbai (India)-400701	Peginterferon beta-1a	BIO/CT/19/000016	28-Oct-19	Phase III comparative trial to evaluate efficacy & safety of R-TPR-075/ Plegridy (Peginterferon beta-1a) in patients with relapsing multiple sclerosis as per Protocol Number.: RLS/MS/2018/06 Version 3.0, Dated 20 Sep 2019	Protocol No.: RLS/MS/2018/06 Version 3.0, Dated 20 Sep-2019	Phase III

21	M/s Intas Pharmaceuticals Limited, BioPharma Division, Plot No. 423/P/A, Sarkhej-Bavla Highway, Village Moraiya, Taluka Sanand, District: Ahmedabad-382213	Trastuzumab	BIO/CT/19/000037	31-Oct-19	Phase I clinical trial entitled "A randomized, double-blind, three-treatment, single dose, parallel group, comparative pharmacokinetic study of biosimilar Trastuzumab (INTP26) with Herceptin® in normal, healthy, adult, male subjects" vide Protocol No. 0936-18, Version 1.0, dated 26.02.2019 for export purpose	Protocol No. 0936-18, Version 1.0, dated 26.02.2019	Phase I
22	M/S Lupin Limited, Kalpataru Inspire, 3rd Floor, off Western Express Highway, Santacruz (East), Mumbai (India) – 400055	Etanercept	BIO/CT/19/000038	05-Nov-19	Phase I clinical trial (BABE study) for Single dose comparative pharmacokinetics study of two different test formulations of Etanercept 50 mg Solution for Injection (YLB113 PFS) administered using a Prefilled Syringe and Etanercept 50 mg Solution for Injection (YLB113 AI) administered using an Auto-Injector Device in healthy adult human subjects vide protocol No. BA18038120, Version No.: 02; Date: 09 October, 2019	Protocol No.: BA18038120, Version No.: 02; Date: 09 October, 2019	Phase I (BABE)
23	M/s Eli Lilly and Company (India) Pvt. Ltd, Plot no. 92, Institutional area, Sector 32 Gurgaon-122001, Haryana, India	Insulin Glargine	BIO/CT/19/000070	07-Nov-19	Phase IV clinical study titled "A Multicenter, OpenLabel, Single-Arm, Phase 4 Study to Assess the Safety of Basaglar in Subjects with Type 2 Diabetes Mellitus in India" vide Protocol I4L-IN-ABEX(b), dated 04-Oct-2019	Protocol I4L-IN-ABEX(b), dated 04-Oct-2019	Phase IV
24	M/s Pfizer Products India Private Limited, The Capital, 1802/1901, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai-400051, Maharashtra, India	Moroctocog alfa	BIO/CT/19/000030	22-Nov-19	Phase IV clinical trial entitled "A single country, multicenter, open-label and non-randomized clinical trial with MOROCTOCO ALFA (AFCC) prophylaxis and treatment of bleeding episodes in previously treated patients with moderate and severe Haemophilia A for a duration of 8 weeks",	Protocol Number: B1831097, Amendment 1, dated 16 September 2019	Phase IV
25	M/s Aurobindo Biologics, (A division of Aurobindo Pharma Ltd.), Unit-17, Survey No.77&78, Indrakaran Village, Kandi Mandal, Sangareddy District, Hyderabad-502329, Telangana, India	Trastuzumab	BIO/CT/19/000059	22-Nov-19	Phase III clinical trial entitled "A Multicenter, Double-Blind, Randomized, Parallel-Group, Active-Controlled, Two Part, Phase III, Global Study to Evaluate the Pharmacokinetics, Efficacy and Safety of BP02 (Trastuzumab) in comparison with Herceptin-EU in Patients with HER2-Positive Early Breast Cancer (EBC) and HER2-Positive Metastatic Breast Cancer (MBC)	Protocol No: CR201-18, Version 1.0, Dated 25.06.2019	Phase III
26	M/s Cadila Healthcare Limited, Zydus Tower, Satellite Cross Road, Sarkhej Gandhinagar Highway Ahmedabad (India) - 380015	Bevacizumab	BIO/CT/19/000074	29-Nov-19	Phase I clinical trial entitled "A randomized, double-blind, parallel, single dose comparative pharmacokinetic study of ZRC-3113 (Zydus Bevacizumab) and Avastin (Bevacizumab) in healthy, adult, male subjects	Protocol No.: BA19086364, Version 01, dated 17 October, 2019 for export purpose	Phase I

27	M/s BioGenomics Limited ,First Floor, Kothari Compound, Opposite Tiku-ji-ni-wadi,,Thane West Thane (India) - 400610	Recombinant Insulin Aspart	BIO/CT/18/000041	30-Nov-19	Phase 3 clinical trial titled "A Randomized, Open Label, Parallel-group, Multi-center Phase 3 Study to compare Efficacy and Safety of Recombinant Insulin Aspart (Manufactured by BioGenomics Limited) with NovoRapid® (Manufactured by Novo Nordisk), in Adult Patients with Diabetes Mellitus	Protocol No.: BGL-IA-CTP301-V1, Version No. 1 Dated 07-MAY-2018	Phase III
28	M/s Virchow Biotech Private Limited	Insulin Glargine	BIO/CT/19/000020	13-Dec-19	An open label, randomized, two-treatment, two sequence, four-period, single dose, full replicate crossover bioequivalence study of VB70G (Insulin Glargine injection) 100 IU/mL of Virchow Biotech, Hyderabad, India and LANTUS (Insulin Glargine injection) 100 IU/mL of Sanofi- Aventis, India in healthy male, adult, human subject under fasting conditions	Protocol No.: 19-026, Version No.: 01, Amendment No. 01, dated 04.06.2019	PK-PD
29	M/s Takeda Pharmaceutical India Pvt. Ltd, The Capital, Unit No. 1504, Plot No. C-70, G-block, Bandra-Kurla Complex, Bandra East Mumbai - 400 051, Maharashtra.	Vedolizumab	BIO/CT/18/000052	26-Dec-19	Phase IV study entitled A Multicenter, Single-arm, open-label, Phase 4 Study to Evaluate the Safety and Efficacy of Vedolizumab in Indian Patients With Ulcerative Colitis and Crohn's Disease	Protocol No. Vedolizumab-4020, Version 01, dated 19.10.2019	Phase IV
30	M/s Biocad India Private Limited	Trastuzumab	1/Phase IV/Biocad/19-BD	26-Dec-19	Phase IV study entitled "A Multicenter Non-Comparative Phase IV study of the safety and Immunogenicity of Herticad (INN: Trastuzumab, CJSC BIOCAD, Russia) Plus Standard Chemotherapy in Patients with Early HER2-Positive Breast Cancer" vie	Protocol No. BCD-022-4, Version 1.1, dated 25.03.2019	Phase IV