



File No. BIO/CT/21/000174

Dated 25-07-2025

To,

M/s. Cliantha Research Limited,
Cliantha Corporate, TP 86, FP 28/1, Off S P Ring Road,
Sarkhej Ahmedabad (India) -382210

Subject: Application for grant of permission to conduct Phase I/III clinical trial entitled – “A Randomized, Double-Blind, Multicenter, Parallel-Group, Active-Controlled Study to Evaluate Pharmacokinetics, Pharmacodynamics, Efficacy and Safety of Ipca’s Rituximab (IPB004) Compared to Reference Biologic (MabThera®) in Subjects with Moderate to Severe Active Rheumatoid Arthritis” as per Protocol No C2A01733, Version 02 dated 13 July 2024 regarding.

Ref. No.: Your Application No. BIO/CT04/FF/2021/29805 dated 30.12.2021

Sir,

With reference to your application No.: BIO/CT04/FF/2021/29805 dated 30.12.2021, please find enclosed herewith the permission in Form CT-06 for conduct of subject clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- (I) Firm is required to submit samples of batches manufactured for clinical trial to NIB for testing and submit test reports to CDSCO.
- (II) CT-21 application shall be made by a person who manufactures new drug in the form of active pharmaceutical ingredient or pharmaceutical formulation for sale or distribution.
- (III) You are required to submit the Clinical study report after completion of study.
- (IV) Clinical trial at each site shall be initiated after approval of the clinical trial protocol and other related documents by the Ethics Committee of that site, registered with the Central Licensing Authority under rule 8
- (V) Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7:

Provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be:

Provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site;

- (VI) In case an ethics committee of a clinical trial site rejects the approval of the protocol, the details of the same shall be submitted to the Central Licensing Authority prior to seeking

approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

- (VII) The Central Licensing Authority shall be informed about the approval granted by the Ethics Committee within a period of fifteen working days of the grant of such approval;
- (VIII) Clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial.
- (IX) Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules.
- (X) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (XI) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal.
- (XII) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination.
- (XIII) Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licensing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI.
- (XIV) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter.
- (XV) In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter.
- (XVI) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial.
- (XVII) The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority.
- (XVIII) The Central Licensing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial.

- (XIX) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (XX) It may kindly be noted that merely granting permission to conduct clinical trial with the drug does not convey or imply that based on the clinical trial data generated with the drug permission to market this drug in the country will automatically be granted to you.

Yours faithfully,
RAJEEV SINGH RAGHUVANSHI
RAGHUVANSHI
Date: 2025.07.25 10:39:18
+05'30'
Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Licensing Authority



FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licensing Authority hereby permits M/s. Cliantha Research Limited, Cliantha Corporate, TP 86, FP 28/1, Off S P Ring Road, Sarkhej Ahmedabad (India) - 382210 to conduct Phase-I/III clinical trial entitled "**A Randomized, Double-Blind, Multicenter, Parallel-Group, Active-Controlled Study to Evaluate Pharmacokinetics, Pharmacodynamics, Efficacy and Safety of Ipca's Rituximab (IPB004) Compared to Reference Biologic (MabThera®) in Subjects with Moderate to Severe Active Rheumatoid Arthritis**" as per Protocol No C2A01733, Version 02 dated 13 July 2024 in the below mentioned clinical trial sites.

2. Details of new drug and clinical trial site [as per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi

Date: 25-JULY-2025

RAJEEV SINGH Digitally signed by RAJEEV
RAGHUVANSHI SINGH RAGHUVANSHI
Date: 2025.07.25 10:39:45
+05'30'

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Rituximab 10mg/mL (500mg/50mL) (rDNA origin) , supplied as a single use vial		
Therapeutic class	Antineoplastic agent (Monoclonal Antibody)		
Dosage form:	IV injection for infusion		
Composition:	Each 50 mL vial contains:		
	Name of Ingredients	Quantity (per 50mL vial)	Function
	Rituximab drug substance In house	500 mg	Active ingredient
	Sodium chloride, Multi compendial	450 mg	Tonicity agent
	Tri-sodium citrate dihydrate, Multi compendial	367.5 mg	Buffering agent
	Polysorbate 80, Multi compendial	35 mg	Surfactant
	Water for Injection (q.s), Type 1 Grade	50mL	Vehicle
Indications:	For the treatment of Rheumatoid Arthritis		

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1.	Prime Care Hospital, B-403, 404, Rudra Arcade B-Wing, Helmet Char Rasta, Near Mayflower Hospital, Drive in road, Ahmedabad, Gujarat - 380052, India	Medilink Ethics Committee Medilink Hospital Research Centre, 132 feet ring road, near shyamal cross road, Ahmedabad Gujarat - 380015 India EC Reg No. ECR/344/INST/GJ/2013/RR-16	Dr. Sunil Maheshwari
2.	Dept of Orthopaedics, OPD Block, Room No 3, Ground Floor, K R Hospital, Mysore Medical College and Reseach Institute, Irwin Road, Mysore, Karnataka - 570001, India	IEC MMC & RI Associated Hospitals Mysore Medical College and Research Institute Irwin Road Mysuru Mysuru (Mysore) Karnataka - 570001 EC Reg. No.: ECR/INST/134/KA/RR 2019	Dr. Neela Gowda VP Patil
3.	Dept of Rheumatology, Institute of Post Graduate Medical Education And Research, Kolkata, West Bengal - 700020, India	IPGME & R Research Oversight Committee IPGME and R 244 Acharya J. C. Bose Road- Kolkata Kolkata West Bengal - 700020 EC Reg. No.: ECR/35/INST/WB/2013/RR-19	Dr. Alakendu Ghosh

4.	Sushruta Multispeciality Hospital & Research Centre Pvt Ltd., P. B. Road, Vidyanagar, Hubballi-580021, Karnataka, India	Sushruta Hospitals Ethics Committee, C/0 Sushruta Multispeciality Hospital & Research Centre Pvt. Ltd., P. B. Raod, Vidyanagar, Hubballi - 580021, Karnataka EC Reg. No.: ECR/372/Inst/KA/2013/RR-19	Dr. Vikram Haridas
5.	V.S. General Hospital, Ellisbridge, Ahmedabad 380006, Gujarat, India	Shrey Hospital Institutional Ethics Committee, Shrey Hospital Private Limited 270/B/5 Near AMCO Bank, Stadium Circle Navrangpura Ahmedabad Gujarat - 380009 India EC Reg No. ECR/1302/Inst/GJ/2019	Dr Dhaiwat Shukla

