



सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
Phone No.: 91-11-23216367
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File No. CT/24/000055

To,

M/s GCT Pharma Research (India) Pvt. Ltd,
7th Floor, Wing-B, Vatika Business Centre, Hiranandani Gardens,
Powai, Mumbai, Maharashtra (India) – 400076.

Sir,

With reference to your application No. GCT/CT04/FF/2024/42808 dated 05-04-2024, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Randomized Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy and Safety of Cenobamate Adjunctive Therapy in Subjects with Primary Generalized Tonic-Clonic Seizures” Protocol No.: YKP3089C025 Version No. 4 Protocol Date 27-OCT-2022 with a total of up-to 10 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

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

- (i) **The firm shall have India specific Independent data and safety monitoring board.**
- (ii) **More number of Government sites shall be included in the study.**
- (iii) **Human biological samples i.e. Human blood (whole), Human urine, Human serum, and Human Plasma related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO.**
- (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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing 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 Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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)** where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
- (xviii)** 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- (xix)** the Central Licencing 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;
- (xx)** the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

- (xxi) Merely granting permission to conduct the clinical trial with the Investigational Drug Product does not convey or imply that, based on the clinical trial study data generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;
- (xxii) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

FORM CT-06
(See rules 22,25,26,29 and 30)

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

1. The Central Licensing Authority hereby permits **M/s GCT Pharma Research (India) Pvt. Ltd, 7th Floor Vatika Business Centre, Supreme Business Park, Hiranandani Garden, Powai Powai (India) - 400076 Telephone No.: 22-42369729 FAX: 22-42019191 Email: U.SAHOO@GCTRIALS.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: YKP3089C025 Version No. 4 Protocol Date 27-OCT-2022** in the below mentioned clinical trial sites [As per Annexure].-

2. Details of new drug or investigational 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 _____

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

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|--|--|
| Names of the new drug or investigational new drug | Cenobamate |
| Therapeutic class: | Antiepileptics |
| Dosage form: | Bottles of Oral Suspension |
| Composition: | YKP3158/ 90.0000 to 110.0000 % In House Specification Active sodium benzoate 90.0000 to 110.0000 % In House Specification Inactive YKP3158/ 0.1000 to 0.5000% In House Specification Individual Impurity YKP3158/ 0.1000 to 3.0000% In House Specification Total Impurity |
| Indications: | Subjects with primary generalized tonic-clonic seizures |

Annexure:

Details of clinical trial site:

| Sr. No. | Names and address of clinical trial site | Ethics committee details | Name of investigator |
|----------------|--|--|--------------------------------------|
| 1. | Sir Ganga Ram Hospital, Department of Neurology, 4th Floor, Sir Gangaram Hospital Marg, Rajinder Nagar, New Delhi –110060 | Ethics Committee Sir Ganga Ram Hospital, Room No. 1643, 6th Floor, Casualty Building, SGRH Marg, Rajinder Nagar, New Delhi-110060, India ECR/20/Inst/DL/2013/RR-19 | Dr Anshu Rohatgi |
| 2. | Central India Cardiology Hospital and Research Institute, Plot No.1, Pioneer Co-Op Housing Society, Gawande Lay-Out, Khamla Ring Road, Opp. Sawarkar Garden, Khamla, Nagpur-440015, Maharashtra, India | IEC Rughwani Child Care Centre and Hospital, Rughwani Child Care Centre and Hospital 22, Sindhu Nagar, Mohanlal Rughwani Marg, Jaripatka, Nagpur-440014 Maharashtra , India ECR/1444/Inst/MH/2020 | Dr Amarjeet Wagh |
| 3. | Getwell hospital & Research Institute, 20/1, Dr Khare Marge dhantoli, Nagpur-440012 | Getwell Ethics Committee, GIEC secretariat, 5th floor, Getwell hospital & Research Institute, 20/1, Dr Khare Marge dhantoli, Nagpur-440012 ECR/109/INST/Maha/2013/RR-19 | Dr Prafulla Shembalkar |
| 4. | Department of Pediatric Neurology, Amrita Institute of Medical Sciences, Cochin Kerala, India, 682041 | Institutional Ethics Committee, Amrita Institute of Medical Sciences, AIMS-Ponekkara. P.O, Kochi, Edappally, Ernakulam, Kerala-682041, India. ECR/129/Inst/KL/2013/RR-19 | Dr Vinayan Kollencheri Puthenveettil |
| 5. | Bhaktivedanta Hospital & Research Institute, Shristi Complex, Bhaktivedanta Swami Marg, Mira Road (East) Thane-401107 | Bhaktivedanta HEC Office, Bhaktivedanta Hospital & Research Institute, ShristiComplex, Bhaktivedanta Swami Marg, Mira Road (East) Thane-401107 ECR/396/Inst/MH/2013/RR-19 | Dr Omkar Hajirnis |
| 6. | Shalinitai Meghe hospital & Research centre | Institutional Ethics Committee Building No-1, Room no-1, Shalinitai Meghe hospital & | Dr Jeevan Kinkar |

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| | | Research centre, Hingna Rd, Wanadongri, Wanadongri ct, Nagpur, Maharashtra 441110 ECR/1603/Inst/MH/2021 | |
| 7. | Dr. G.M. Taori Memorial Central India Institute of Medical Science, 88/2 Bajaj Nagar, Nagpur - 440010, Maharashtra, India | IEC Rughwani Child Care Centre and Hospital, Rughwani Child Care Centre and Hospital 22, Sindhu Nagar, Mohanlal Rughwani Marg, Jaripatka, Nagpur-440014 Maharashtra, India ECR/1444/Inst/MH/2020 | Dr Neeraj Baheti |
| 8. | PMSSY, Super Speciality Hospital, New Tharagupet, Banglore-560002 | Institutional Ethics Committee of Banglore Medical College & Research Institute Fort, Krinsha Rajendra Rd, Banglore-560002 ECR/302/KA/2013/RR-20 | Dr Praveen Kumar |
| 9. | Masina Trust Hospital, Sant Savta Marg, Byculla, (East) Mumbai Mumbai City Maharashtra -400027 India | Masina Trust Hospital, Sant Savta Marg, Byculla (East) Mumbai Mumbai City Maharashtra -400027 India ECR/1179/Inst/MH/2019/RR-22 | Dr Ashish Gosar |
| 10. | Acharya Vinoba Bhave Rural Hospital Sawangi (Meghe), Wardha Maharashtra-442004 | Institutional Ethics Committee Administrative Block, University Office, DMIHER, (DU), Sawangi (Meghe), Wardha-442107, Maharashtra, India. ECR/440/Inst/MH/2013/RR-19 | Dr Tushar Patil |
| 11. | All India Institute of Medical Science, Plot No. 2, Sector 20, MIHAN, Sumthana, Nagpur-441108, Maharashtra, India | Institutional Ethics Committee, All India Institute of Medical Science, MIHAN, Sumthana, Nagpur-441108, Maharashtra, India. ECR/1392/Inst/MH/2020 | Dr Shikha Jain |
| 12. | Saachi Children hospital Prajapati Brahma Marg, near Akashganga Apartment, Sanskar Nagar, Majura Gate, Surat, Gujarat 395002 | Ethics Committee Unique Hospital-Multispeciality & Research Institute Opp-Kiran Motor, Nr Canal, Civilhospital Char Rasta-Sosya Circle lane, Off Ring Road, Surat-395002 ECR/595/Inst/GJ/2014/RR-20 | Dr Ritesh Shah |
