

Tele No.011-23236965

Fax.No.011-23236973

F. No. ND/MA/25/000036
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-11 0002

To

M/s Eris Lifesciences Ltd.
1st Floor-101, Shivarth Ambit, Opp. Janvi Bunglows,
Nr. Mann Party Plot, Sindhubhavan Road
Gujarat – 380054

Subject: Application for grant of permission to conduct Phase-III Clinical trial titled- “A Multicenter, Randomized Open-Label, Comparative, Active Controlled, Prospective Clinical Trial to Investigate Efficacy and Safety of Cenobamate Tablet as an Adjunctive Treatment in Patients with Refractory Epilepsy Suffering from Focal Onset Seizures with or Without Secondary Generalisation (Clinical Trial Protocol No. ICS/ERI/2024-008, Ver no. 2.0 dated: 19.04.2025- regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2025/48294** dated **13.03.2025**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/28/2025** to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

This permission is subject to the conditions, as mentioned below.

Yours faithfully

RAJEEV SINGH Digitally signed by RAJEEV
RAGHUVANSHI SINGH RAGHUVANSHI
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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Conditions of permission

- (i) 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;
- (ii) 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;

- (iii) 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;
- (iv) 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;
- (v) 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;
- (vi) 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;
- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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 of the New Drugs and Clinical Trials Rules, 2019;

- (xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules 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;
- (xii) 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 the 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;
- (xiii) 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 authorized 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;
- (xiv) 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;
- (xv) The Laboratory owned by any person or a company or any other legal entity and utilized 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;
- (xvi) 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;
- (xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.
- (xix) The Informed Consent Document including ICF and Patient Information Sheet should clearly mention in understandable language about the details of the drug therapy that the patient may or may not receive.
- (xx) The firm shall submit Bioequivalence study report to CDSCO for review by the committee before initiating the Phase III clinical trial.

FORM CT-06*(See rules 22, 25, 26, 29 and 30)***PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG****CT Permission No. CT/ND/28/2025**

The Central Licensing Authority hereby permits **M/s Eris Lifesciences Ltd., 1st Floor-101, Shivarth Ambit, Opp. Janvi Bunglows, Nr. Mann Party Plot, Sindhubhavan Road, Gujarat-380054, Telephone No.: 91-7969661063, FAX: 07930179404, E-Mail: ganesh.boddu@erislifesciences.com** to conduct clinical trial of the new drug as per **Protocol No. ICS/ERI/2024-008 Version no. 2.0 dated: 19.04.2025** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:

| | |
|---|--|
| Names of the new drug or investigational new drug: | Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg |
| Therapeutic class: | Anticonvulsant |
| Dosage form: | Tablets |
| Composition: | <p>Cenobamate Tablets 12.5 mg Each uncoated tablets contains Cenobamate.....12.5 mg Excipients.....q.s.</p> <p>Cenobamate Tablets 25 mg Each film coated tablets contains Cenobamate.....25 mg Excipients.....q.s.</p> <p>Cenobamate Tablets 50 mg Each film coated tablets contains Cenobamate.....50 mg Excipients.....q.s.</p> <p>Cenobamate Tablets 100 mg Each film coated tablets contains Cenobamate.....100 mg Excipients.....q.s.</p> <p>Cenobamate Tablets 150 mg Each film coated tablets contains Cenobamate.....150 mg Excipients.....q. s</p> <p>Cenobamate Tablets 200 mg Each film coated tablets contains Cenobamate.....200 mg Excipients.....q.s.</p> |
| Indications: | For the treatment of focal-onset seizures in adult patients |

| Details of clinical trial sites- | | |
|---|--|---|
| Sr. No. | Name of Principal Investigator & Trial Sites | Ethics Committee Name/ Registration Number |
| 1. | Dr. Patil Nahush Dilip Signus Hospital, 5thFloor, Atlanta Shoppers, Pathardi Road, Pathardi Phata, Nashik 422010, Maharashtra | Signus Hospital Ethics Committee 5thFloor, Atlanta Shoppers, Pathardi Road, Pathardi Phata, Nashik 422010, Maharashtra India ECR/1773/Inst/MH/2022 |
| 2 | Dr. Bala Pradeep Boyidapu Visakha Institute of Medical Sciences, Department of Neurology Hanumanthawaka Junction, Chinagadilli, Visakhapatnam-530040, Andhra Pradesh | Visakha Institute of Medical Sciences, S.No 97/2 Hanumanthawaka, Chinagadilli, Visakhapatnam-530040, Andhra Pradesh India ECR/1421/Inst/AP/2020 |
| 3 | Dr. Bhuma Vengamma Sri Devaraj Urs Academy of Higher Education & Research.(SDUAHER) Department Of Neurology, Tamaka, Kolar, Karnataka-563103 | Central Ethics Committee SDUAHER Chennai Bengaluru Tirupati Highway Tamaka KolarKolar Karnataka -563103 ECR/425/Inst/KA/2013/RR-20 |
| 4 | Dr. Mona Gajre Lokamanya Tilak Muncipal Medical College and General Hospital, Dr. Babasaheb Amedkar Road, Sion Mumbai, Maharashtra-400022 | Institutional Ethics Committee Lokmanya Tilak, Dr. Babasaheb Amedkar Road, Sion Mumbai Maharashtra-400022 ECR1266/Lokmanya/Inst/MH/2013/RR-24 |
| 5 | Dr. Suryaprabha Turaga Nizams Institute of Medical Sciences, Panjagutta, Hyderabad-500082, Telangana | NIMS Institutional Ethics Committee Panjagutta, Hyderabad-500082 Telangana ECR/303/Inst/AP/2013/RR-24 |
| 6 | Dr. Janardan Indira Gandhi Institute of Medical Sciences Sheikhpura Raja Bazar Patna, Bihar -800014. | Institutional Ethics Committee Indira Gandhi Institute of Medical Sciences Sheikhpura, Raja Bazar Patna Bihar - 800014 India ECR/640/Inst/BR/2014/RR-20 |
| 7 | Dr. Ashis Das Peerless Hospitex Hospital And Research Center Limited, 360 Panchasayar, Kolkatta-700094, West Bengal | Clinical Research Ethics Committee Peerless Hospitex Hospital And Research Center Ltd, 360 Panchasayar Kolkatta, West Bengal-700094 ECR/232/Inst/WB/2013/RR-24 |

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.

RAJEEV SINGH Digitally signed by RAJEEV SINGH RAGHUVANSHI
RAGHUVANSHI Date: 2025.09.16 15:46:19 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

New Delhi