

F. No. ND/MA/24/000013
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 Bajaj Healthcare Ltd.,
602-606, Bhoomi Velocity Infotech Park,
Road No. 23, Wagle Industrial Estate,
Thane West, Maharashtra - 400604

Subject: Application for grant of permission to conduct Phase-III Clinical trial titled- "A phase III, multicenter, randomized, double-blind, parallel-group clinical trial to compare the efficacy and safety of the Cenobamate tablets as adjunctive therapy versus Eslicarbazepine in focal onset seizures (Clinical Trial Study No. LCT-04/23 Ver no. 2.0 dated: 20.09.2024, Amendment no. 1.0 dated 27.02.2025- regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2024/41651** dated **25.01.2024**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/04/2025** 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

RAGHUVANSHI

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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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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.

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/04/2025**

The Central Licensing Authority hereby permits **M/s Bajaj Healthcare Ltd., 602-606, Bhoomi Velocity Infotech Park, Road No. 23, Wagle Industrial Estate, Thane West, Maharashtra – 400604, Telephone No.: 8655353090, FAX: 8655353090, E-mail: import@bajajhealth.com** to conduct clinical trial of the new drug as per **Study No. LCT-04/23 Version no. 2.0 dated: 20.09.2024, Amendment no. 1.0 dated 27.02.2025** 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:	Antiepileptics
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:		It is indicated for the treatment of partial-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 Dilip Nagrwal Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan	Institutional Ethics Committee Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan ECR/1156/Inst/RJ/2018/RR-22
2	Dr Arvind Kumar Kankane (Neurology) Maharani Laxmi Bai Medical College, Jhansi (UP)-284128	Ethics Committee MLB Medical College & Associated Hospital, MLB Medical College, Kanpur Road, Jhansi (UP)-284128, India ECR/1393/Inst/Up/2020
3	Dr Bala Pradeep Boyidapu Visakha Institute of Medical Sciences Hanumanthavaka, Visakhapatnam-530040, Andhra Pradesh	Visakha Institute of Medical Sciences, S.No. 97/2, Chinnagadilli Village, Hanumanthavaka, Visakhapatnam-530040, Andhra Pradesh ECR/142/Inst/AP/2020
4	Dr Shalin Shah Sardar Vallabhbhai Patel Institute of Medical Sciences and Research (Ahmedabad)	Institutional Ethics Committee, Smt. NHL Medical College, Ahmedabad ECR245/Inst/G.J/2013/RR-19
5	Dr. Menka Jha All India Institute Of Medical Sciences (Odisha)	Ethics Committee AllMS, Sijua, Dumduma, Patrapada, Bhubaneswar, Odisha-751019 ECR/534/Inst/OD/2014/PR-20
6	Dr Anil Kumar Devanaboina Anil Neuro & Trauma Centre, Vijaywada (Andhra Pradesh)	Capital Hospitals Institutional Ethical Committee, Capital Tree Health Care Pvt Ltd, D.No. 15-177/1, Poranki Penamaluru Manadal, Vijayawada Krishna, penamarulu NTR Andhra Pradesh-521137 ECR/1994/Inst/AP/2024
7	Dr. Shah Mohammad Faisal Gangasheel Advance Medical Research Institute, Bareilly (Uttar Pradesh)	Institutional Ethics Committee, Director office ground floor, Gangasheel Advance Medical Research Institute, C17 Deen Dayal Puram, Bareilly, UP-243122 ECR/1319/Inst/UP/2019
8	Dr Pradeep R M.S Ramaiah Medical College and Hospital Bangalore (Karnataka)	Ethics Committee, M.S Ramaiah Medical college and Hospitals, M S Ramaiah Nagar, MSRIT Post,

		Bangalore, Karnataka-560054, India ECR/215/Inst/KA/2013/RR-22
9	Dr Neeraj Jain King Edward Memorial Hospital Mumbai (Maharashtra)	Institutional Ethics Committee, UG/PG Hostel Building, Ground Floor, KEM Hospital campus, Dr. S.S. Rao, Road, Parel, Mumbai ECR/229/Inst/MH/2013/RR-24
10	Dr. Ravindranadh C M, National Institute of Mental Health and Neuro Sciences Bengaluru (Karnataka)	Ethics Commiittee, Ground Floor, Dean's Office, Administrative Block, NIMHANS, Hosur Road, Bengaluru, Pin- 560029 EC/NEW/Inst/2023/KA/0264

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
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