

**F. No. ND/MA/24/000023**  
**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. MSN Laboratories Private Limited,  
MSN House, Plot No: C-24, Industrial Estate,  
Sanath Nagar, Hyderabad-500018.

**Subject: Application for grant of permission to conduct Phase-III Clinical trial titled- "A Randomized, Multicentre, Open Label, Active Controlled, Parallel Group, Phase III Clinical Study to Evaluate the Efficacy and Safety of Cenobamate Tablets in Comparison with Eslicarbazepine acetate Tablets in Adult Patients suffering from Focal Onset Seizures (Clinical Trial Protocol No. MSN/CT/CENO/11/23, Ver no. 2.0 dated: 30.07.2025- regarding.**

Sir,

With reference to your application no. **ND/CT21/FF/2024/41738** dated **10.02.2024**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/29/2025** 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

Date: 2025.10.03 18:03:00  
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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.
- (xx) The firm shall include detailed safety evaluation of subjects and causality assessment of adverse drug reactions in the protocol.

**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/29/2025**

The Central Licensing Authority hereby permits **M/s. MSN Laboratories Private Limited, MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad-500018, Phone: +91-4030438712, 8302, Fax: +914030438667, E-mail: krreddy@msnlabs.com** to conduct clinical trial of the new drug as per **Protocol No. MSN/CT/CENO/11/23, Ver no. 2.0 dated: 30.07.2025** in the below mentioned clinical trials sites.

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

<b>Names of the new drug or investigational new drug:</b>	<b>Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg</b>
<b>Therapeutic class:</b>	<b>Anticonvulsant</b>
<b>Dosage form:</b>	Tablets
<b>Composition:</b>	<b>Cenobamate Tablets 12.5 mg</b> Each tablet contains Cenobamate.....12.5 mg Excipients.....q.s.  <b>Cenobamate Tablets 25 mg</b> Each tablet contains Cenobamate.....25 mg Excipients.....q.s.  <b>Cenobamate Tablets 50 mg</b> Each tablet contains Cenobamate.....50 mg Excipients.....q.s.  <b>Cenobamate Tablets 100 mg</b> Each tablet contains Cenobamate.....100 mg Excipients.....q.s.  <b>Cenobamate Tablets 150 mg</b> Each tablet contains Cenobamate.....150 mg Excipients.....q. s  <b>Cenobamate Tablets 200 mg</b> Each tablet contains Cenobamate.....200 mg Excipients.....q.s.

<b>Indications:</b>		It is indicated for the treatment of partial-onset seizures in adult patients
<b>Details of clinical trial sites-</b>		
<b>Sr. No.</b>	<b>Name of Principal Investigator &amp; Trial Sites</b>	<b>Ethics Committee Name/ Registration Number</b>
1.	<b>Dr. Dhondji Madhukar Shrimantrao (Neurology)</b> Gajanan Hospital and Critical Care Centre, Near Gajanan Maharaj Temple chowk, Opposite Axis bank, Besides LIC Office, Garkheda, Aurangabad-431005.	Ethics Committee of Ishwar Institute of HealthCare, Ishwar Institute of Health Care, 3rd Floor, Plot No.07, Gut No. 6/1 Padhegaon, Beside Panjabi Bhavan Jaysingpura Aurangabad Maharashtra-431002 India <b>ECR/988/Inst/MH/2017/RR-20</b>
2	<b>Dr. Sawale Vishal Madhukar (Neurology)</b> Neuro Plus Brain & Spine Advanced Neurology Centre, Ahilyadevi Holkar Road, Near Tupsakhre Lawns, Mumbai Naka Nashik 422002.	Muktai Hospital Institutional Ethics Committee, Muktai Hospital, Plot no.11, Shivaji Nagar, Nashik-Pune Road, Nashik-422006, Maharashtra, India <b>ECR/251/Inst/Maha/2013/RR-24</b>
3	<b>Dr. Mohammad Faisal Shah (Neurology)</b> Gangasheel Advanced Medical Research Institute, C-17 Deen Dayal Puram Bareilly Uttar Pradesh 243122	Institutional Ethics Committee Gangasheel Advanced Medical Research Institute, C17, Deen Dayal Puram Near OBC Bank Bareilly, Uttar Pradesh - 243001 India <b>ECR/1319/Inst/UP/2019/RR-24</b>
4	<b>Dr. Yeole Amit Bhalchandra (Neurology)</b> Supe Heart & Diabetes Hospital and Research Centre, Opp Adhar Ashram, Near rungta school, Gharpure Ghat, Ashok Stambh, Nashik ,Maharashtra-422002	Supe Hospital Ethics Committee, Supe Heart Diabetes Hospital And Research Centre, Opp. Adharashram, Gharpure Ghat Near Rungtha School, Ashok Stambha Nashik, Maharashtra - 422002 India <b>ECR/272/Inst/MH/2013/RR-24</b>
5	<b>Dr. Shukla Vikas (Neurosurgery)</b> Panacea Multi Super Speciality Hospital Pvt. Ltd., 117/473, L-Block Kakadeo Between Neercheer, Chauraha Dabal Pulia, Kanpur, Uttar Pradesh-208005.	Institutional Ethics Committee, Lifetron Hospital O/PR-2, O Block, A Was Vikash Keshavpuram, SCH-1, Near KDMA, World School, Kanpur Nagar, Kanpur, Uttar Pradesh- 208019, India <b>ECR/2044/Inst/UP/2025</b>
6	<b>Dr. Praveen Kumar S (Neurology)</b> BMCRI Super Speciality Hospital, (PMSSY), Victoria Hospital campus KR market, bangalore - 560002, Karnataka.	Ethics Committee of BMCRI, Bangalore Medical College and Research Institute, Fort KR Road Bangalore, Urban Karnataka - 560002, India. <b>ECR/302/Inst/KA/2013/RR-20</b>
7	<b>Dr. Lalla Rakesh Shyam (Neurology)</b> Ashirwad Hospital and Research Centre, Near Jijamata Udyan, Maratha Section, Ulhasnagar-421004.	Ashirwad Ethics Committee Ashirwad Hospital and Research Centre, Maratha Section Near Jijamata Udyan, Ulhasnagar, Thane, Maharashtra - 421004

		<b>ECR/247/Inst/MH/2013/RR-24</b>
8	<b>Dr. Saroja A.O (Neuro medicine)</b> KLE's Dr. Prabhakar kore Hospital & MRC, Nehru Nagar, Belagavi-590010	Institutional Ethics Committee, KLE University, Dr. PK Hospital and MRC, Nehru Nagar, Belagavi (Belgaum), Karnataka - 590010 India <b>ECR/211/Inst/KA/2013/RR-24</b>
9	<b>Dr. Amruth (Neurology)</b> Karnataka Medical College & Research Institute, Consultant room no.2, 1st floor, PMSSY Building, KMCRI, Hubballi-580021, Karnataka.	KMCRI Ethics Committee, Karnataka Medical College and Research Institute, Office of the Principal Vidyanagar Hubballi, Dharwad Karnataka - 580021 India. <b>ECR/486/Inst/KA/2013/RR-25</b>
10	<b>Dr. Anand Rajendra Someshwar (Psychiatry)</b> Anand Multispeciality Hospital and Research Center, 4th Floor, Sarthak mall, Mahatma Mandir Road, Sargasan, Gandhinagar-382421, Gujarat, India.	Anand Ethics Committee Anand Multispecialty Hospital and Research Centre 4th Floor, Sarthak Mall, Mahatma Mandir Road Sargasan Cross Road Gandhinagar Gandhinagar, Gujarat - 382421 India <b>ECR/1144/Inst/GJ/2018/RR-21</b>
11	<b>Dr. V.N. Madhava Rao (Neurology)</b> Mahatma Gandhi Memorial Hospital, Sherpura, Warangal, Telangana 506002.	Kakatiya Institutional Ethics Committee, Kakatiya Medical College, SVP road Rangampet street, Warangal, Urban, Warangal, Telangana-506007, India <b>ECR/840/Inst/TG/2016/RR-20</b>
12	<b>Dr. S.S.V.V Narasinga Rao (General medicine)</b> Government Medical College & Government General Hospital, Srikakulam-532001, Andhra Pradesh - India	Institutional Ethics Committee, Government General Hospital, Srikakulam, Shanti Nagar Colony Balaga, Srikakulam, Andhra Pradesh - 532001 India <b>ECR/2088/Inst/AP/2025</b>
13	<b>Dr. Bala Pradeep Boyidapu (Neurology)</b> Visakha Institute of Medical Sciences, Department of Neurology, Visakha Institute of Medical Sciences, Hanumanthavaka, Chinnagadhili, Visakhapatnam-530040, Andhra Pradesh, India.	Visakha Institute of Medical Sciences (VIMS), S. No 97/2, Hanumanthawaka Chinagadilli Village, Visakhapatnam (India) - 530040 India <b>ECR/1421/Inst/AP/2020</b>
14	<b>Dr. Agrawal Nilesh Radheshyam (Neurosurgery)</b> New Era Hospital, Central Avenue Road, Near Telephone exchange Chowk, Quets Colony, Near Jalaram Mandir, Nagpur-440008	New Era Hospital Ethics Committee, Near Jalaram Mandir, Queta Colony Near, Telephone exchange chowk, Central Avenue Road, Nagpur Nagpur, Maharashtra - 440008 India <b>ECR/896/Inst/MH/2017/RR-25</b>
15	<b>Dr. Amarkumar Misra (Neurology)</b> North Bengal Medical College and Hospital, Sushrutanagar Siliguri, Darjeeling-734012, West Bengal,	Institutional Ethics Committee, North Bengal Medical College And Hospital, Susrutanagar Siliguri, Darjeeling, West Bengal - 734012

	India.	India <b>ECR/1701/Inst/WB/2022</b>
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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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**(Dr. Rajeev Singh Raghuvanshi)**  
**Central Licensing Authority**

**New Delhi**