Tele No.011-23236965
Fax.No.011-23236973

F. No. ND/MA/24/000115
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 Enaltec Labs Pvt. Ltd,
1701, 17th Floor, Kesar Solitaire,
Plot No. 5, Sector 19, Sanpada,
Navi Mumbai, Maharashtra,
India (400705)

Subject: Grant of permission to conduct Phase III Clinical Trial title " A Phase III, Randomized, Open Label, Active Controlled, Prospective, Parallel Group, Comparative, Multicentric Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Remimazolam Besylate 20 mg Lyophilized Powder for Injection in Comparison with Midazolam Injection for the Induction and Maintenance of Procedural Sedation in Patients Undergoing Short Surgical Procedures (protocol no .CT/2024/36, Version No:00 dated June 20, 2024)" -reg.

Sir,

With reference to your application no. **ND/CT21/BO/2024/44684 dated 02.08.2024,** please find enclosed herewith the permission in **Form CT-06, No. CT/ND/31 /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
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.07 12:58:30 +05'30'

(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 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/31 /2025

The Central Licensing Authority hereby permits **M/s Enaltec Labs Pvt. Ltd., 1701, 17th Floor, Kesar Solitaire, Plot No. 5, Sector-19, Sanpada, Navi Mumbai (India)-400705 Telephone No.: 2267507000 FAX: 2267507070 E-Mail INFO@ENALTEC.COM** conduct clinical trial of the new drug as per **" Protocol no. CT/2024/36, Version No: 00 dated June 20, 2024** 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:~~	**Remimazolam Besylate 20mg lyophilized powder for injection,**
Therapeutic class:	Ultra short acting benzodiazepine
Dosage form:	Lyophilized Powder for solution for injection
Composition:	Each Vial Contains: Remimazolam 20milligram (mg) (Equivalent to 27.2mg Remimazolam besylate) Excipients .....q.s. **Preservative Free** Reconstitute with 8.2 ml of 0.9% sodium chloride injection, IP. Discard unused solution after 8 hours.
Indications:	Remimazolam Besylate 20mg lyophilized powder for injection is indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	**Dr Ajay Kumar Patwa ,** Department of Medicine (Gastro Unit) King George s Medical University , Chowk , Lucknow – 226003, Utter Pradesh	Institutional Ethics Committee, King George's Medical University, Shahmina Road, Chowk, Lucknow-226003, Uttar Pradesh, ECR/262/Inst/UP/2013/RR-19
2	**Dr. Gursaran Kalif Sidhu**, Sidhu Hospital Pt.Ltd., G.T. Road, Doraha-141421, Dist. Ludhiana, Punjab.	Institutional Review Board, Sidhu Hospital, Room No. 100, G.T. Road, Doraha, Ludhiana-141421, Punjab. ECR/722/Inst/PB/2015/RR-21

3	**Dr. Prasanta Kumar Das** All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019. Odisha	Institutional Ethics Committee, All India Institute of Medical Sciences, Sijua, P/o Patrapada, Bhubaneswar-751019, Khordha,Odisha. ECR/534/Inst/OD/2014/RR-20
4	**Dr. Patel Riteshkumar Sankarlala** Health1 Super Speciality Hospital, Near Venitian Villa, Shilaj Circle, S.P. Ring Road, Thaltej,Ahmedabad-380059, Gujarat.	Health1 Super Speciality Hospital Ethics Committee, Health1 Super Speciality Hospital ,Block C, GF To 8 Floor, Shilaj 23/73, On S.P. Ring Road, Near Shilaj Circle, Shilaj,Ahmedabad-380059, Gujarat. ECR/1666/Inst/GJ/2022
5	**Dr. Shah Parth Kirtikumar,** Sheth Vadilal Sarabhai General Hospital & Sheth Chinai Maternity Hospital, Madalpur Gam, Paldi Road, Ellisbridge, Paldi,Ahmedabad-380006, Gujarat	Institutional Ethics Committee Aatman Hospital, Aatman Hospital,5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal-Ghuma Main Road, Bopal,Ahmedabad-380058, Gujarat. ECR/1565/Inst/GJ/2021
6	**Dr. Gupta Dhaval Vinaykumar** Mission Gastro Hospital, 6th Floor, Golden Icon Above Hundai Showroom Besides, 603, 132 Feet Ring Road, Jodhpur Village, Ahmedabad-380015, Gujarat	Sangini Hospital Ethics Committee C/o Sangini Hospital, First Floor, Santorini Square, B/H Abhishree Complex, Opp. Star Bazar Lane, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat. ECR/147/Inst/GJ/2013/RR-19
7	**Dr. Patel Krunal Ramanlal** GCS Medical College, Hospital and Research Centre, Opp. DRM Office, Near Chamunda Bridge, Naroda Road,Ahmedabad-380025, Gujarat	Institutional Ethics Committee, GCS Medical College, Hospital and Research Centre, Opp. DRM Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad-380025, Gujarat. ECR/339/Inst/GJ/2013/RR-19
8	**Dr. M. Uma Devi** Department of Gastroenterology, NPR Block, 1st Floor, Liver Care Unit, Osmania General Hospital, Osmania Medical College, Afzalgunj,Hyderabad-500012, Telangana.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana. ECR/300/Inst/AP/2013/RR-19
9	**Dr. Vivek Nayak** Department of Anaesthesiology,	Institutional Ethics Committee – Mysore Medical College and Research Institute

	K.R. Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka.	and Associated Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysuru-570001, Karnataka. ECR/134/Inst/KA/2013/RR-19

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 RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.07 12:59:32 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority
Stamp

New Delhi