

**F. No. ND/MA/22/000191**  
**Government of India**  
**Directorate General of Health Services**  
**Central Drugs Standard Control Organization**  
**New Drugs Division**

FDA Bhawan, Kotla Road,  
New Delhi-110002

Dated:

27 JAN 2023

To,  
M/s Hetero Labs Limited,  
Hetero Corporate, 7-2-A2, Industrial Estates,  
Sanathnagar, Hyderabad-500018, Telangana. India.

**Subject:** Grant of permission to conducting Phase III clinical trial study entitled "A Phase III, Multi-Center, Randomized, Double Blind, Active-controlled, Parallel group study to evaluate the Efficacy and Safety of Vonoprazan 20mg tablets compared to Pantoprazole 40mg tablets in Patients with Gastroesophageal Reflux Disease (GERD)" -Regarding.

**CT NOC No.: CT-06/ND/08/2023**

Sir,

With reference to your Application No. ND/CT21/FF/2022/35284 dated 19.12.2022 please find enclosed herewith the permission in **Form CT-06, No. CT/ND/08/2023** 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,



(Dr. V. G. Somani)  
Central Licensing Authority

**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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority electronically in the SUGAM portal;
- (ix) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing 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 Licensing 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorized by the Central Licensing 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 Licensing 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 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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;
  - (xvi) The Central Licensing 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) It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.



**FORM CT-06**

(See rules 22, 25, 26, 29 and 30)

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

The Central Licensing Authority hereby permits **M/s Hetero Labs Limited, 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad-500018, India Telephone No.: 91-40-23704923 FAX: 91-40-23801902** to conduct clinical trial of the new drug as per protocol No. **HCR/III/ VONONERD/12/2022, Version No 1.0, dated 08-12-2022** in the below mentioned clinical trial sites.

**2. Details of new drug or investigational new drug:**

<b>Names of the new drug or investigational new drug:</b>	<b>Vonoprazan Tablets 10mg/20mg</b>
<b>Therapeutic class:</b>	Potassium competitive acid blocker
<b>Dosage form:</b>	Oral Dosage Form - Tablet
<b>Composition:</b>	Each film coated tablets contains Vonoprazan Fumarate equivalent to Vonoprazan 10mg Each film coated tablets contains Vonoprazan Fumarate equivalent to vonoprazan 20mg
<b>Indications:</b>	Vonoprazan is indicated in the: • Treatment of reflux esophagitis (RE) Other indications: • Treatment of gastric ulcer (GU) • Treatment of duodenal ulcer (DU) • Prevention of recurrence of gastric ulcer or duodenal ulcer during low-dose aspirin administration. • Prevention of recurrence of gastric ulcer or duodenal ulcer during NSAIDs administration. • Adjunct to Helicobacter pylori eradication associated with: Gastric ulcer, duodenal ulcer, gastric MALT lymphoma, idiopathic thrombocytopenic purpura, the stomach after endoscopic resection of early stage cancer, or Helicobacter pylori gastritis.

**Details of clinical trial sites-**

<b>Sr. No</b>	<b>Name of Principal Investigator &amp; Trial sites</b>	<b>Ethics Committee Name/Registration Number</b>
1	<b>Dr. P. Shravan Kumar, Professor &amp; HOD</b> MBBS, M.D Gen. Medicine ,D.M (Gastroenterology) Gandhi Hospital Inpatient, Block,5 <sup>th</sup> Floor, Department of Gastroenterology, Musheerabad, Secundrabad, Telangana-500003	Institutional Ethics Committee, Gandhi Medical/Hospital College, Gandhi Hospital, Musheerabad, Secundrabad, Telangana-500003  <b>ECR/180/Inst/AP/2013/RR-19</b>

2	<b>Dr. T. V. Pradeep Kumar, Assistant Prof.</b> MBBS, DNB Gen. Medicine, D.M Gastroenterology, Great Eastern Medical School and Hospital Ragolu, Srikakulam - 532484 Andhra Pradesh, India	Institutional Ethics Committee Great, Eastern Medical School and Hospital Ragolu, Srikakulam -532484 Andhra Pradesh, India. <b>ECR/1521/Inst/AP/2021</b>
3	<b>Dr. Manoj Kumar, Assistant Professor</b> MBBS, MD Gastroenterology Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan <b>ECR/1156/Inst/RJ/2018/RR-22</b>
4	<b>Dr. Rahul Bhargami, Consultant Gastroenterologist</b> MBBS, M.D, DNB(Gastroenterology) Hitech Multispeciality Hospital Sector3-D, Plot No 1180, Gh Road ,Nr.Gh-11/2 Bus Stand, Gandhi nagar, Gujarat -382003	Hi tech Ethics Committee Hi tech Multispeciality Hospital Sector3-D, Plot No.1180, Gh Road Nr. Gh-11/2 Bus Stand, Gandhi nagar, Gujarat -382003 <b>ECR/1057/Inst/GJ/2018/RR-21</b>
5	<b>Dr. Vatsal Kirti kumar Mehta, Consultant Gastroenterologist</b> MBBS, M.D, DNB, (Gastroenterology) Shashvat Surgicare Hospital Plot no.3,4 Shyam residency, Kудasan, District Gandhi nagar 38242, Gujarat.	Parth institutional Ethics committee, Parth Hospital, Galaxy Arcade, E/408-411,4Th Floor, Galaxy Road, Near Galaxy Cinema, Naroda, Ahmedabad <b>ECR/1530/Inst/GJ/2021</b>
6	<b>Dr. Sunil Kumar Mahavar Professor</b> MBBS, MD (General Medicine) CO-I: Dr. Sudhir Maharshi MBBS, DNB, DM (Gastroenterology) SMS Medical College and Attached Hospital Department of Medicine, G-1 Dhanvantri OPD, Block SMS Hospital, Jaipur 302004	Ethics Committee SMS Medical College and Attached Hospitals, JLN Marg. Jaipur, Rajasthan, -302004 <b>ECR/26/Inst/RJ/2013/RR-19</b>
7	<b>Dr. Manas Kumar Mondal, Assistant Professor</b> MBBS, MD (Medicine) DM Gastroenterology) Nil Ratan Sircar Medical College and Hospital Kolkata 138, AJC Bose Road, Kolkata 700014, West Bengal. India	Institutional Ethics Committee Nil Ratan Sircar Medical College and Hospital Kolkata.138, AJC Bose Road, Kolkata 700014 West Bengal. India <b>ECR/609/Inst/WB/2014/RR-20</b>
8	<b>Dr. Tryambak Samanta, Assistant Professor</b> MBBS, MD (Medicine) DM Gastroenterology) Medical College and Hospital, Kolkata. Department of Gastroenterology, 88, College Street, Kolkata 700073, West Bengal, India.	Institutional Ethics Committee for Human Research, Medical College and Hospital, Kolkata 88, College Street, Kolkata 700073, West Bengal, India. <b>ECR/287/Inst/WB/2013/RR-19</b>

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.

  
(Dr. V. G. Somani)

Central Licensing Authority

New Delhi

Date: .....

27 JAN 2023