File No. SND/MA/20/000008
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Subsequent New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 11 MAR 2020

To,

M/s Exemed Pharmaceuticals.,
Block No. 628 (A & B), ECP Canal Road,
Vill-Luna, Taluka-Padra, Dist. Vadodara – 391440,
Gujarat.

Subject: "Grant of permission to undertake Phase III clinical trial of New Drug – Acotiamide SR 300 mg tablet" - Reg.

CT NOC No.: CT/SND/18/2020

Sir,

With reference to your Application No. SND/CT21/FF/2019/17978 please find enclosed herewith the permission in Form CT-06, CT NOC No. **CT/SND/18/2020** 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 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 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 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 authorised 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 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 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) Age of the subjects to be within 18-50 years.

(xx) Primary Endpoint should be the composite score of Rome IV parameters evaluated on seven point Likert scale.

(xxi) In the secondary endpoint: Elimination rate (Score 0) shall be assessed for the Rome IV symptoms of upper abdominal pain, postprandial fullness, early satiation, and heartburn at the end of 04 weeks treatment period and follow up period.

(xxii) Revised protocol as above should be submitted before initiation of the Phase III Clinical Trial.

(xxiii) You should submit the BA study report before the committee prior to initiation of 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 NOC NO.: CT/SND/18/2020

The Central Licensing Authority hereby permits **M/s Exemed Pharmaceuticals., Block No. 628 (A & B), ECP Canal Road, Vill-Luna, Taluka-Padra, Dist. Vadodara – 391440, Gujarat** to conduct clinical trial of the new drug ~~or investigational new drug~~ as per **Protocol No. EP/ACO/CT/19/001, Version No: 00, Dated 20/12/2019** in the below mentioned clinical trial sites.

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

Names of the new drug:	Acotiamide Sustained Release Tablets 300 mg
Therapeutic class:	Prokinetic agent
Dosage form:	Film Coated Bilayer Sustained Release Tablets
Composition:	Each Film Coated Bilayer Sustained Release Tablets Contains: Acotiamide Hydrochloride.....300 mg Excipients.....q.s.
Indications:	For the treatment of bloating after meals, epigastric bloating and early satiety in functional dyspepsia.

Details of clinical trial sites

Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1	Dr. Hrishikesh Bora, Down Town Hospital, Dispur, G.S. Road, Guwahati – 781006, Assam.	Ethics Committee, Down Town Hospital, 6th Floor, 1st Building, G.S. Road, Dispur, Guwahati – 781006, Assam. ECR/549/Inst/AS/2014/RR-17
2	Dr. K. Sunil Naik, Department of Medicine, Government Medical College & Government General Hospital (Old RIMSGGH), Srikakulam – 532001, Andhra Pradesh.	Institutional Ethics Committee Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001, Andhra Pradesh, ECR/492/Inst/AP/2013/RR-16
3	Dr. P. Shravan Kumar, 5th Floor, Department of Gastroenterology, In Patient Block Gandhi Medical College/Hospital, Musheerabad, Secunderabad – 500003.	Institutional Ethics Committee, Gandhi Medical College/Hospital, Musheerabad, Secunderabad – 500003. ECR/180/Inst/AP/2013/RR-19

4	Dr. Parmar Kartikeya Ganpatlal, Department of Medicince, B.J. Medical College and Civil Hospital, Asarwa, Ahmedabad – 380016, Gujarat.	Institutional Ethics Committee, B.J. Medical College and Civil Hospital, Asarwa, Ahmedabad – 380016, Gujarat. ECR/72/Inst/GJ/2013/RR-19
5	Dr. Sagar Vivek Redkar, Redkar Hospital and Research Centre, Mumbai –Goa, Highway, Oshalbag, Village-Dhargal, Tal-Pernem, Goa – 403513.	Redkar Hospital Institutional Ethics Committee, (RHIEC), Redkar Hospital and Research Centre, Mumbai –Goa, Highway, Oshalbag, Village-Dhargal, Tal-Pernem, Goa – 403513. ECR/902/Inst/GA/2018
6	Dr. Shankar Ramgouda Patil, Prakash Institute of Medical Sciences & Researc, Urun-Islampur (PIMS & R), Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali-Maharashtra – 415409.	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Researc, Urun-Islampur (PIMS & R), Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali-Maharashtra – 415409. ECR/1052/Inst/MH/2018
7	Dr. Vijay Kumar Shivajirao Patil, Apple saraswati Multispeciality Hospital, CROM Clinical Research and Medical Tourism Pvt Ltd., 804/2, 805/2, Circuit House to Kadamwadi Road, Bhoslewadi Kolhapur – 416003, Maharashtra.	Asmh Institutional Ethical Committee, Apple saraswati Multispeciality Hospital, CROM Clinical Research and Medical Tourism Pvt Ltd., 804/2, 805/2, Circuit House to Kadamwadi Road, Bhoslewadi Kolhapur – 416003, Maharashtra. ECR/1237/Inst/MH/2019

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
Stamp

Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

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Date: 11 MAR 2020