Tele No.011-23236965
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F. No. ND/MA/25/000002
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 Exemed Pharmaceuticals,
Plot No. 133/1 & 133/2 G.I.D.C,
Selvas Road, Vapi – 396195.
Gujarat.

Subject: A Multicentric, Prospective, Parallel Group, Randomized, Active Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Gefapixant Tablets 45 mg in Comparison with Benzonatate Capsules 100 mg in Adult Patients for the Treatment of Refractory or Unexplained Chronic Cough (Protocol no. CT/2024/49, version 00 dated: 18.12.2024-regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2025/47141 dated 07.01.2025**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/22/2025** 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: 2025.08.26 12:24:32 +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 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/22/2025

The Central Licensing Authority hereby permits **M/s Exemed Pharmaceuticals, Plot No. 133/1 & 133/2 G.I.D.C, Selvas Road, Vapi – 396195. Gujarat, Telephone No.: 912606617777 FAX: 912606617799** to conduct clinical trial of the new drug as per **Protocol no. CT/2024/49, version 00 dated: 18.12.2024** 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:~~	**Gefapixant Tablets 45 mg**
Therapeutic class:	**P2X3 receptor antagonist**
Dosage form:	Tablets
Composition:	**Gefapixant Tablets 45 mg** Each film coated tablet contains: Gefapixant Citrate equivalent to Gefapixant 45mg
Indications:	Indicated in adults for the treatment of refractory or unexplained chronic cough

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	**Dr. Manish Kumar Jain (Tuberculosis & Respiratory Diseases)** Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan	Institutional Ethics Committee, Maharaja Agrasen Super speciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan **ECR/1222/Inst/RJ/2019/RR-22**
2	**Dr. Neeraj Gupta (Tuberculosis & Chest Diseases)** Department of Respiratory Medicine (Chest and T.B.) Jawahar Lal Nehru (J.L.N) 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**
3	**Dr. Shyam Narain Gupta (Tuberculosis & Chest Diseases)** Sanjivini Hospital and Research Center, CP-23 Viraj Khand, Near Hahnemann Chauraha, Gomati Nagar, Lucknow-226010, Uttar Pradesh.	Sanjivani Lung Centre Ethics Committee, Sanjivani Lung Centre, 2/4, Vastu Khand, Kathautha Chauraha, Beside Fire Station, Gomti Nagar, Lucknow-226010, Uttar Pradesh **ECR/963/Inst/UP/2017/RR-20**
4	**Dr. Amitabh Das Shukla (Tuberculosis & Respiratory Diseases)** Department of Pulmonary, Motilal Nehru Medical College Associated Swarooprani	Institutional Ethics Committee, Motilal Nehru Medical College, George Town, Prayagraj, Allahabad-211002, Uttar Pradesh

	Nehru Hospital, Prayagraj-211001, Uttar Pradesh	**ECR/922/Inst/UP/2017/RR-22**
5	**Dr. Amit Asati (Respiratory Diseases)** SMC Heart Institute and IVF Research Centre, Infront of BSNL Office, Vidhan Sabha Road, Khamardih, Raipur-492007, Chhattisgarh	SMC Heart Institute Institutional Ethics Committee, SMC Heart Institute and IVF Research Centre, Infront of BSNL Office, Vidhan Sabha Road, Khamardih, Raipur-492007, Chhattisgarh **ECR/1522/Inst/CG/2021**
6	**Dr. Himanshu Shashikant Pophale (Pulmonary Medicine)** Ace Hospital & Research Centre, Sr. No. 32/2A, Gulwani Maharaj Road, Erandwane, Pune-411004, Maharashtra	Institutional Ethics Committee - Ace Hospital, ACE Hospital and Research Centre, 32/2 A, Erandawane, Gulwani Maharaj Road, Pune-411004, Maharashtra **ECR/1836/Inst/MH/2023**
7	**Dr. Shraddha Rane (Pulmonary Medicine)** Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Tal-Pernem, Goa-403513	Redkar Hospital Institutional Ethics Committee (RHIEC), Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Pernem, North Goa-403513, Goa **ECR/902/Inst/GA/2018/RR-21**
8	**Dr. Anita Saibannavar (Pulmonary Medicine)** Department of Pulmonary, Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416012, Maharashtra.	Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College Institutional Ethics Committee 2 (RCSMGMCIEC2), Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Building No. 2, Quarter No. 3, Room No. 7, Dasara Chowk, Town Hall, Bhausingji Road, Kolhapur-416007, Maharashtra **ECR/703/Inst/MH/2015/RR-20**
9	**Dr. Vijaykumar Shivajirao Patil (General Medicine)** Prakash Institute of Medical Sciences & Research (PIMS&R), Urun-Islampur, Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali-415409, Maharashtra	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Research (PIMS&R), Urun-Islampur, Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali- 415409, Maharashtra **ECR/1052/Inst/MH/2018/RR-21**
10	**Dr. Vasireddy Aruna (Pulmonary Medicine)** Department of Pulmonary Medicine, Govt. Siddhartha Medical College, Ring Road, Gunadala, Vijayawada-520008, Krishna, Andhra Pradesh	Institutional Ethics Committee SMC and GGH, Siddhartha Medical College & Govt. General Hospital, Ring Road, Gunadala, Vijayawada 520008, Krishna, Andhra Pradesh **ECR/633/Inst/AP/2014/RR-19**
11	**Dr. Ranganath T. G (Pulmonary Medicine)** All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, 492099, Chhattisgarh	Institutional Ethics Committee All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, 492099, Chhattisgarh. India**ECR/714/Inst/CT/2015/RR-21**
12	**Dr. Raja Bhattacharya, (General Medicine)** Medical College , Kolkata 88, College Street Kolkata, West Bengal - 700073	Institutional Ethics Committee Medical College, Kolkata 88, College Street Kolkata, West Bengal - 700073 **ECR/287/Inst/WB/2013/RR-24**
13	**Dr. Magar Pankaj Kondiram (Respiratory Diseases)** Pulse Multispecialty Hospital Survey No. 51/7/B/1 Vishwa Arcade, Bombay	Institutional Ethics Committee Pulse Multispecialty Hospital Survey No. 51/7/B/1 Vishwa Arcade, Bombay Bangalore Highway, At Post Narhe

	Bangalore Highway, At Post Narhe, Pune Maharashtra - 411041	Pune Maharashtra – 411041 **ECR/1339/Inst/MH/2020/RR-25**
14	**Dr. Vulli Venkatesh (Pulmonary Medicine)** Visakha Institute of Medical Sciences (Vims) , S.No 97/2, Hanumanthawaka Chinagadilli Village Visakhapatnam (India) - 530040	Institutional Ethics Committee Visakha Institute of Medical Sciences, Visakhapatnam, Andhra Pradesh **ECR/1421/Inst/AP/2020**
15	**Dr. Sirisha Peddi (General Medicine)** Gandhi Medical College and Hospital Gandhi Medical College Secunderabad Hyderabad Telangana - 500003.	Institutional Ethics Committee Gandhi Medical College and Hospital Gandhi Medical College Secunderabad Hyderabad Telangana – 500003 **ECR/180/Inst/AP/2013/RR-24**
16	**Dr. Chappa Rama Naga Bhushana Rao, (Tuberculosis & Respiratory Diseases)** Government Hospital for Chest and Communicable Diseases (GHCCD), Visakhapatnam, Andhra Pradesh.	Institutional Ethics Committee King George hospital Maharanipeta Collector Office Junction Visakhapatnam Andhra Pradesh - 530002 **ECR/197/Inst/KGH/2013/RR-20**

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

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(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

New Delhi