

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

**F. No. ND/MA/24/000058**  
**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 Sun Pharma Laboratories Limited,  
Sun Pharma Advanced Research Centre (SPARC)  
Tandalja Vadodara (India) – 390012

Subject: Application for grant of permission to conduct Phase-III Clinical trial titled- “A Phase 3 Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Gefapixant in Adult Patients with Chronic Cough” vide Protocol no. ICR/24/001, Version No. 1.0 dated: 08.02.2024-regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2024/42628** dated **29-MAR-2024**; please find enclosed herewith the permission in **Form CT-06, vide No. CT/ND/17/2024** 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  
**(Dr. Rajeev Singh Raghuvanshi)**  
**Drugs Controller General (India)**

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL ORGANISATION, 2.5.4.20=42d7189b1c9981bbsa263a473d028f8b11b680a91f08773480400a43ee361b, postalCode=110002, st=Delhi, serialNumber=6575a41d940985d8f032a6-c020d011673cf412d1a126ea9fa65701124a19013, cn=RAJEEV SINGH RAGHUVANSHI  
Date: 2024.09.18 14:20:25 +05'30'

**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) **Firm, is granted permission to conduct Phase-III clinical trial, with following changes in inclusion criteria,**
    - a) **At S.No. 1, aged 18-65 years instead of aged 18 years or older,**
    - b) **At S.No. 3, CT thorax instead of Chest X-ray or CT thorax.****Other contents of the protocol remain same.**
  - (xx) **The firm should submit Bioequivalence study report to CDSCO for review by the SEC committee, before initiating the 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**

The Central Licensing Authority hereby permits **M/s Sun Pharma Laboratories Limited, Sun Pharma Advanced Research Centre (SPARC), Tandalja Vadodara (India)–390012 Telephone: (91-265) 661 5500, Fax: (91-265) 235 4897 E-Mail: IRA@sunpharma.com** to conduct clinical trial of the new drug as per Protocol Number: **Protocol no. ICR/24/001, Version No. 1.0 dated: 08.02.2024** 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>Gefapixant tablets 45 mg</b>
<b>Therapeutic class:</b>		<b>P2X3 receptor antagonist</b>
<b>Dosage form:</b>		Tablets
<b>Composition:</b>		Each film coated tablet contains Gefapixant Citrate equivalent to Gefapixant.....45 mg Excipients.....q.s.
<b>Indications:</b>		Indicated in adults for the treatment of refractory or unexplained chronic cough.
<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. Sheth Vaishal Dineshbhai</b> (Consultant Pulmonologist) Department of Pulmonary Medicine, Sheth Vadilal Sarabhai General Hospital & Sheth Chinai Maternity Hospital, Ahmedabad	Institutional Ethics Committee, Aatman Hospital, Ahmedabad <b>ECR/1565/Inst/GJ/2021</b>
2	<b>Dr. Ashish Gautam</b> (Professor) Department of Medicine, S.N. Medical College, Agra	Institutional Ethics Committee, S.N. Medical College, Agra <b>ECR/1409/Inst/UP/2020</b>
3	<b>Dr. Mahendra Pal Singh</b> (Assistant Professor) Post Graduate Department of Medicine, GSVM Medical College, Kanpur	Ethics Committee, GSVM Medical College, Kanpur <b>ECR/680/Inst/UP/2014/RR-20</b>
4	<b>Dr. Jitendra Shukla (Associate Professor)</b> Department of Medicine, Motilal Nehru Medical College, Prayagraj	Institutional Ethics Committee, MLN Medical College, Prayagraj <b>ECR/922/Inst/UP/2017/RR-22</b>
5	<b>Dr. Amanul Haque</b> (Assistant Professor and Registered Medical Officer) Department of General Medicine,	Ethics Committee, NRS Medical College and Hospital, Kolkata <b>ECR/609/Inst/WB/2014/RR-20</b>

	NRS Medical College and Hospital, Kolkata	
6	<b>Dr. Patel Chintan Bharatkumar</b> (Consultant Physician) Health 1 Super Speciality Hospital, Ahmedabad	Ethics Committee, Health 1 Super Speciality Hospital, Ahmedabad <b>ECR/1666/Inst/GJ/2022</b>
7	<b>Dr. Deepak Bansal</b> (Senior Consultant) VincareHospital, 100 Feet Road Opp, Petrol Pump Bathinda Punjab –151001, India.	Institutional Ethics Committee, Vincare Hospital, Bathinda <b>ECR/1657/Inst/PB/2022</b>
8	<b>Dr. Anjali R. Nath</b> (Consultant Pulmonologist) Citizen Hospital, Bangalore	Institutional Ethics Committee, Citizen Hospital, Bangalore <b>ECR/1591/Inst/KA/2021</b>
9	<b>Dr. Toke Sahebrao Kondiba</b> (Consultant Pulmonologist) Ojas Multispecialty Hospital, Pune	Ethics Committee, Ojas Multispecialty Hospital, Pune <b>ECR/1284/Inst/MH/2019</b>
10	<b>Dr. Shilkande Pravin Govind</b> (Consultant Physician) Supe Heart and Diabetes Hospital and Research Centre, Nashik	Ethics Committee, Supe Hospital, Nashik <b>ECR/272/Inst/MH/2013/RR-19</b>
11	<b>Dr. Bharat Das</b> (Senior Consultant- General Medicine) Sparsh Hospitals and Critical Care Private Limited, Bhubaneswar	Institutional Ethics Committee, Sparsh Hospitals and Critical Care Private Limited, Bhubaneswar <b>ECR/68/Inst/OR/2013/RR-22</b>
12	<b>Dr. Diptikant Sahoo</b> (Consultant Pulmonologist) Department of Pulmonology, Shanti Memorial Hospital, Cuttack	Ethics Committee, Shanti Hospital, Cuttack <b>ECR/1749/Inst/OD/2022</b>
13	<b>Dr. Sarat Kumar Behera</b> (Senior Consultant Pulmonology and TB) Department of TB and Chest, KIDS Hospital, Bhubaneswar	KIDS Ethics Committee, Bhubaneswar <b>ECR/1132/Inst/OD/2018/RR-22</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.

RAJEEV SINGH  
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION, ou=CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION,  
2.5.4.20=428718981c0981bb5a263a4a73d025f4b11b680a91f  
08773480400a43ee361b, postalCode=110002, st=Delhi,  
serialNumber=657f5e47d940985d8f01bdc902d0e1fe73cf12a  
1a126ca946e701124a19013, cn=RAJEEV SINGH  
RAGHUVANSHI  
Date: 2024.09.18 14:21:23 +05'30'

(Dr. Rajeev Singh Raghuvanshi)  
Central Licensing Authority  
Stamp

New Delhi