

F. No. ND/MA/24/000125
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002

To

**M/s Sun Pharma Laboratories Limited,
Sun Pharma Advanced Research Centre (SPARC),
Tandalja Vadodara (India) - 390012**

Subject: Grant of permission to conduct Phase III Clinical Trial title “A Prospective, Multicenter, Randomized, Assessor-Blind, Parallel-Group, Active-Controlled, Phase III Study to Evaluate the Efficacy and Safety of Esaxerenone Tablets for Treatment of Uncontrolled or Resistant Hypertension.” (Protocol no. ICR/24/016, Version No. 1.0 dated 10th December 2024) -regarding.

Reference: Letter Ref. No. ND/CT21/FF/2024/44894, Dated: 30-AUG-2024.

Sir,

With reference to your application no. ND/CT21/FF/2024/44894, Dated: 30-AUG-2024 please find enclosed herewith the permission in Form CT-06, No. CT/ND/06/2025 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 Digitally signed by RAJEEV
RAGHUVANSHI SINGH RAGHUVANSHI
Date: 2025.05.09 12:35:28
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(Dr. Rajeev Singh Raghuvanshi)
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) 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.
 - (xx) **All the Investigators should be Cardiologist.**

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/06/2025**

The Central Licensing Authority hereby permits **M/s Sun Pharma Laboratories Limited ,Sun Pharma Advanced Research Centre (SPARC) Tandalja Vadodara (India) - 390012 Telephone No.: 0265-6615500 FAX: 0265-2354897 E-Mail : INDIA.REGULATORYAFFAIRS@SUNPHARMA.COM** to conduct Phase III clinical trial of the new drug **Clascoterone Cream 1% w/w** as per **Protocol no. ICR/24/016, Version No. 1.0 dated 10th December 2024** in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Esaxerenone Tablets 1.25 mg or 2.5 mg or 5 mg	
Therapeutic class:	Nonsteroidal mineralocorticoid receptor antagonist	
Dosage form:	Tablets	
Composition:	Each uncoated tablet contains Esaxerenone.....1.25 mg or 2.5 mg or 5 mg Excipients q.s	
Indications:	Indicated for the treatment of hypertension	
Details of clinical trial sites-		
Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/Registration Number
1.	Dr. Barik Rama Chandra (Professor & HOD), Department of Cardiology, All India Institute of Medical Sciences, Bhubaneswar	Institutional Ethics Committee, All India Institute of Medical Sciences, Bhubaneswar. ECR/534/Inst/OD/2014/RR-25
2.	Dr. Neelam Dahiya(Associate Professor), Department of Cardiology, Postgraduate Institute of Medical Education and Research, Chandigarh	Institutional Ethics Committee, Postgraduate Institute of Medical Education and Research, Chandigarh. ECR/25/Inst/CH/2013/RR-20
3.	Dr. Abhishek Sachdeva (Associate Professor), Department of Cardiology, Motilal Nehru Medical College, Prayagra	Institutional Ethics Committee, Motilal Nehru Medical College, Prayagra. ECR/922/Inst/UP/2017/RR-22

4.	Dr. Santosh Kumar Sinha (Associate Professor), LPS Institute of Cardiology & Cardiac Surgery – GSVM, Kanpur	Institutional Ethics Committee, LPS Institute of Cardiology and Cardiac Surgery, Kanpur ECR/2062/Inst/UP/2025
5.	Dr. Krishna Mala Konda Reddy P. (Professor and HOD) Department of Cardiology, Osmania Medical College & General Hospital, Hyderabad.	Institutional Ethics Committee, Osmania Medical College, Hyderabad. ECR/300/Inst/AP/2013/RR-24
6.	Dr. Pradeep Kumar Meena (Associate Professor) Department of Cardiology, SMS Hospital, Jaipur.	Ethics Committee S.M.S. Medical College and Attached Hospitals, Jaipur. ECR/26/Inst/RJ/2013/RR-24
7.	Dr. Subhash Chandra (Assistant Professor and HOD), Clinical Research Department, Uttar Pradesh University of Medical Sciences, Etawah	Institutional Ethics Committee, Uttar Pradesh University of Medical Sciences, Etawah ECR/1830/Inst/UP/2023
8.	Dr. Swapan Kumar Halder (Associate Professor), Department of Cardiology, Nil Ratan Sircar Medical College & Hospital, Kolkata	Ethics Committee, N.R.S. Medical College and Hospital, Kolkata. ECR/609/Inst/WB/2014/RR-20
9.	Dr. Patel Sandarbh Piyushkumar (Consultant Cardiologist), Medilink Hospital, Ahmedabad.	Medilink Ethics Committee, Ahmedabad. ECR/344/Inst/GJ/2013/RR-24
10.	Dr. Gawande Gajanan Dnyanba (Consultant Cardiologist, Asian Institute of Medical Sciences, Dombivli	Suraksha Ethics Committee, Asian Institute of Medical Sciences Hospital, Dombivli. ECR/644/Inst/MH/2014/RR-20
11.	Dr. Ingole Suraj Subhash (Consultant Cardiologist), Maeer's Vishwaraj Hospital, Pune	Institutional Ethics Committee, Maeers Vishwaraj Hospital, Pune. ECR/1138/Inst/MH/2018/RR-21
12.	Dr. Kharche Milind Nivrutti (Chief Interventional Cardiologist), Research Department, United CIIGMA Institute of Medical Sciences Pvt. Ltd., Aurangabad	Ethics Committee Kodlikeri Memorial Hospital and Group of CIIGMA Hospital (ECKMHGCH), Aurangabad

13.	Dr. Suryawanshi Suresh Punam (Consultant Cardiologist), Supe Heart and Diabetes Hospital and Research Centre, Nashik.	Supe Hospital Ethics Committee, Nashik. ECR/272Inst/MH/2013/RR-24
14.	Dr. Prakas Chandra Mondal (Senior Consultant, Interventional Cardiologist) Apollo Multispeciality Hospitals Limited, Kolkata	Institutional Ethics Committee, Apollo Multispeciality Hospitals Limited, Kolkata. ECR/373/Inst/WB/2013/RR-19
15.	Dr. Gurmukhani Sunil Nichaldas (Consultant Cardiologist), Health 1 Super Specialty Hospital, Ahmedabad	Health 1 Super Speciality Hospital Ethics Committee, Ahmedabad. ECR/1666/Inst/GJ/2022
16.	Dr. Hundekari Sachin Tukaram (Consultant Cardiologist), Clinical Research Department, Ojas Multispeciality Hospital, Pune	Ojas Multispecialty Hospital Ethics Committee, Pune. ECR/1284/Inst/MH/2019/RR-24
17.	Dr. Chaudhari Subhash Devjibhai (Consultant Cardiologist), SGS Super Speciality Hospital, Gandhinagar.	Health 1 Super Speciality Hospital Ethics Committee, Ahmedabad. ECR/1666/Inst/GJ/2022
18.	Dr. Jena Manabhanjan (Senior Consultant) Department of Cardiology, Utkal Hospital, Bhubaneswar	Institutional Ethics Committee, Utkal Hospital, Bhubaneswar. ECR/1920/Inst/OD/2024
19.	Dr. Afsar Pasha(Consultant), Cardiology Department, Santosh Hospital, Bengaluru	Santosh Hospital-Institutional Ethics Committee, Bengaluru. ECR/1062/Inst/KA/2018/RR-21

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 Digitally signed by RAJEEV SINGH RAGHUVANSHI
RAGHUVANSHI Date: 2025.05.09 12:35:09 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority

New Delhi