

Dairy No.:
ND/CT04/FF/2021/28536
dated 14.10.2021

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F. No. ND/CT/21/000085
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
New Drugs Division

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

06 DEC 2021

To

M/s Sun Pharmaceutical Industries Limited,
Tandalja, Vadodara, Gujarat (India) – 390012

Subject: Grant of permission to undertake Phase-IV Clinical Trial titled “A Prospective, Multi-center, Single-arm, Phase IV Study to Assess the Safety and Efficacy of Cariprazine Capsules in Adult Patients with Schizophrenia and Acute Treatment of Manic or Mixed Episodes Associated with Bipolar I Disorder” - regarding.

CT NOC No.: CT/ND/190/2021

Sir,

With reference to your application no. ND/CT/21/000085 dated 14.10.2021, please find enclosed herewith the permission in Form CT-06, No. CT/ND/190/2021 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 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 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) **Firm should include the rescue medication in the protocol.**
- (xx) **Accordingly revised CT protocol should be submitted to CDSCO.**

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 Pharmaceutical Industries Limited, Tandalja, Vadodara, Gujarat (India) - 390012** Telephone No.: 912656615500, E-Mail: IRA@sunpharma.com to conduct clinical trial of the **new drug** as per protocol version no. 1.0, dated 01.10.2021 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:	Cariprazine Capsules in strength 1.5 mg, 3.0 mg, 4.0 mg and 6 mg	
Therapeutic class:	Antipsychotic	
Dosage form:	Capsules	
Composition:	Each Capsule contains - Cariprazine Hydrochloride equivalent to Cariprazine1.5 mg/3 mg/ 4.5mg/6mg	
Indications:	For the treatment of: Schizophrenia in adults. Acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.	
Details of clinical trial sites-		
Sr. No.	Name of Principal Investigator & Trial sites	Ethics Committee Name/ Registration Number
1.	Dr. Susanta Kumar Padhya (Additional Professor) Department of Psychiatry, AIIMS, Bhubaneswar.	Institutional Ethics Committee, AIIMS Bhubaneswar ECR/534/ Inst /OD/2014/RR-20
2.	Prof. (Dr.) Pradeep Kumar Saha (Director & HOD) Institute of Psychiatry IPGME & R SSKM Hospital, Kolkata.	IPGME & R Research Oversight Committee, Kolkata ECR/35/Inst/WB/2013/RR-19
3.	Dr. Shah Nilesh Bhagwandas (Professor and Head) Department of psychiatry, Lokmanya Tilak Muncipal Medical College and General Hospital Mumbai	Institutional Ethics Committee Lokmanya Tilak, Mumbai. ECR/266/Lokmanya/Inst/MH/2013/RR-19
4.	Dr. Siddharth Shetty A (Associate Professor) Department of psychiatry, Father Muller Medical College Hospital, Mangalore	Father Muller institutional Ethics Committee, Mangalore ECR/540/Inst/KA/2014/RR-20

5.	Prof. (Dr.) Deepanjali Medhi, (Prof. & HOD) Department of Psychiatry, Guwahati Medical college & Hospital, Guwahati	Institutional Ethics Committee, Guwahati Medical college & Hospital, Guwahati ECR/1470/Inst/AS/2020
6.	Dr. Siddhartha Sankar Saha (Asst. Professor) Department of Psychiatry, Nil Ratan Sircar Medical College and Hospital, Kolkata.	Ethics Committee, N.R.S. medical, Kolkata ECR/609/Inst/WB/2014/RR-20
7	Dr. Shri Gopal Goyal (Associate Professor) Department of Psychiatry, S.P. Medical college & A.G. of Hospitals, Bikaner	Ethics Committee, S.P. Medical college ECR/27/SP/Inst/RJ/2014/RR-19
8	Dr. Dhanajay Chaudhary (Professor and HOD) Department of Psychiatry, GSVM Medical Collage, Kanpur	Ethics Committee, GSVM Medical Collage, Kanpur ECR/680/Inst/UP/2014/RR-20
9	Dr. Pattojoshi Amrit (Professor and HOD) Hi-Tech Medical College and Hospital, Bhubaneswar	Institutional Ethics Committee Hi-Tech Medical College and Hospital, Bhubaneswar ECR/273/Inst/OR/2013/RR-20
10	Dr. Sudhir Hebbar (HOD) Department of Psychiatry, Sapthagiri institute of medical Science and Research centre, Bangalore	Institutional Ethics Committee Sapthagiri Hospital Bangalore ECR/583/Inst/KA/2014/RR-20
11	Dr. Keertish N (Professor and HOD) Department of Psychiatry, BGS Global Institute of Medical Sciences, Bengaluru	Institutional Ethics Committee, BGS Global Institute of Medical Sciences, Bengaluru ECR/1307/Inst/KA/2019
12	Dr. Vikhram Ramasubramanian (Consultant Psychiatrist) Ahana Hospital LLP, Madurai	Ethics Committee- Radianz Healthcare & Research, Ahana Hospital, Madurai ECR/546/Inst/TN/2014/RR-20
13	Dr. Ghughe Sanjay Devidasrao (Consultant Psychiatrist) Sukhkarta MindCare Clinic, Aurangabad	Ethics Committee, Ajanta Superspeciality Hospital, Aurangabad. ECR/1499/Inst/MH/2021
14	Dr. Manish Jain (Consultant Psychiatrist) Dr. B.L. Kapur Memorial Hospital, New Delhi	Dr. B.L. Kapur Memorial Hospital, Ethics Committee, New Delhi ECR/3/BLK/Inst/DL/2013/RR-19

15	Dr. Yadav Ramashanker Rammurti (Consultant Psychiatrist), Shivam Hospital Ahmedabad.	Shivam Ethics Committee, Ahmedabad. ECR/63/Inst/GJ/2013/RR-20
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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.

New Delhi

Date:

06 DEC 2021


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

Dr. V. G. SOMANI
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

