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

F. No. ND/MA/25/000012
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. MSN Laboratories Private Limited,
MSN House, Plot No: C-24, Industrial Estate,
Sanath Nagar, Hyderabad - 500 018.
Telangana.

Subject: Grant of permission to conduct Phase-III Clinical trial of drug Olanzapine/Samidorphan Tablets 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg vide protocol titled "A phase-III, Randomized, Double-Blind, Placebo Controlled, Multi-Center, Two-Arm, Clinical Trial to Assess the Efficacy, Safety, and Tolerability of FDC of Olanzapine/Samidorphan (5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, and 20 mg/10 mg) in Adults with Schizophrenia and Bipolar I Disorder." Protocol Number: 005/FDC-OL-SA/MSN/2025, Version No. 2.0 dated: 21/JAN/2026 - regarding.

Sir,

With reference to your application no. **ND/CT21/FF/2025/47486 dated 24.01.2025,** please find enclosed herewith the permission in **Form CT-06 vide No. CT/ND /26/2026** 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: 2026.07.24 16:24:26 +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.

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/26/2026

The Central Licensing Authority hereby permits, **M/s. MSN Laboratories Private Limited, MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad. Pin code- 500018. Telangana. India** to conduct clinical trial of the new drug as per **Protocol Number: 005/FDC-OL-SA/MSN/2025, Version No. 2.0 dated: 21/JAN/2026** 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:~~	**Olanzapine and samidorphan Tablets 5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg and 20 mg/10 mg**
Therapeutic class:	Opioid antagonist
Dosage form:	Tablets
Composition:	1.**Olanzapine and samidorphan Tablets 5 mg/10 mg** Each tablet contains 5 mg of Olanzapine USP and 10 mg Samidorphan (Equivalent to 13.6 mg of Samidorphan LMalate) 2. **Olanzapine and samidorphan Tablets 10 mg/10 mg** Each tablet contains 10 mg of Olanzapine USP and 10 mg Samidorphan (Equivalent to 13.6 mg of Samidorphan L-Malate) 3. **Olanzapine and samidorphan Tablets 15 mg/10 mg** Each tablet contains 15 mg of Olanzapine USP and 10 mg Samidorphan (Equivalent to 13.6 mg of Samidorphan L-Malate) 4. **Olanzapine and samidorphan Tablets 20 mg/10 mg** Each tablet contains 20mg of Olanzapine USP and 10 mg Samidorphan (Equivalent to 13.6 mg of Samidorphan L-Malate)
Indications:	It is indicated for the treatment of • Schizophrenia in adults • Bipolar I disorder in adults • Acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate • Maintenance monotherapy treatment

Details of clinical trial sites-		
Sr. No.	**Name of Principal Investigator & Trial Sites**	**Ethics Committee Name/ Registration Number**
1.	**Dr. Pavan Kumar Padala** (MD Psychiatry) Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, Uttar Pradesh	Institutional Ethics Committee, SRMSIMS, Bareilley, Ramurthipuram, Bareilly Nainital Road, Bareilly, Uttar Pradesh-243202 **ECR/1067/Inst/UP/2018/RR-21**
2	**Dr. Bhirud Mahesh Govindrao** (DNB psychiatry) Swastik Dhadiwal Hospital, Trambak Road, Opp. Thakkar Bazzar, Matoshree Nagar, Nashik-422002	Shree Institutional Ethics Committee, Swastik Dhadiwal Hospital, Trambak Road, Opp. Thakkar Bazzar, Matoshree Nagar, Nashik-422002 **ECR/II49/Inst/MH/2018/RR-21**
3	**Dr. Suyog Vijay Jaiswal** (MD Psychiatry) All India Institute of Medical Sciences, Nagpur, Maharashtra - 441108 India.	Institutional Ethics Committee for Clinical Trial, All India Institute of Medical Sciences, Nagpur, M/S Director AIIMS, Plot No 2, Sector 20 1st floor, OPD building, MIHAN, Nagpur, Maharashtra - 441108 India **ECR/1392/Inst/MH/2020/RR-25**
4	**Dr Asish Mukhopadhyay** (MD Psychiatry) NRS Medical College & Hospital, 138 AJC Bose Road, Kolkata-700014, West Bengal, India	Ethics Committee, N.R.S. Medical College NRS Medical College And Hospital, NRS Medical College 138, A.J.C Bose Road , Kolkata West Bengal – 700014.India **ECR/609/Inst/WB/2014/RR-25**
5	**Dr. P. Lakshmi Prasuna** (DNB psychiatry) ACSR Government Medical College and Hospital, Nellore 524004, Andhra Pradesh, India.	Institutional Ethics Committee, ACSR Government Medical College and Hospital, opposite A.C. Stadium, Darga Mitta, Nellore- 524004, Andhra Pradesh, India. **ECR/961/Inst/AP/2017/RR-25**

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
Date: 2026.07.24 16:24:54 +05'30'

(Dr. Rajeev Singh Raghuvanshi)
Central Licensing Authority
Stamp

New Delhi