

Nil

File No. FDC/MA/21/000061. ✓

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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

To,

M/s. Synokem Pharmaceuticals Pvt. Ltd.,
Plot No. 35-36, Sec. 6A, Integrated Industrial Estate,
Ranipur (Bhel), Haridwar, Uttarakhand-249403.

30 JUL 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Duloxetine (delayed release pellets) IP + Pregabalin IP (20mg + 75mg, 20mg + 50mg, 30mg + 75mg) hard gelatin capsules (Vide protocol no. CRPL/CT/21/00 version no. 00, dated: 18.02.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on date 02.03.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-104/2021** under the provision of Drugs and Cosmetics Act and Rule. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithful



(Dr. V. G. Somar)
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 the 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:
 - i. 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;
 - ii. Provided further that the approving Ethics Committee and the clinical trial site, 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;

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**Permission no.: **CT-06-104/2021**

1. The Central Licencing Authority hereby permits **M/s. Synokem Pharmaceuticals Pvt Ltd., Plot No. 35-36, Sec. 6A, Integrated Industrial Estate, Ranipur (Bhel) Haridwar, Uttrakhand-249403.** (Name and full address with contact details of the applicant) to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. CRPL/CT/21/007, version no. 00, dated 18.02.2021)** in the below mentioned clinical trial sites.
2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
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.

Place: New Delhi

Date:
30 JUL 2021

Central Licencing Authority

Stamp
Dr. V. G. SOMANI
 Drugs Controller General (India)
 Dte. General of Health Services
 Ministry of Health and Family Welfare
 FDA Bhawan, Kirti Road, I.T.O.
 New Delhi-110002

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Duloxetine (as delayed release pellets) IP + Pregabalin IP (20mg + 75mg, 20mg + 50mg & 30mg + 75mg) hard gelatin capsules
Therapeutic class:	Neurological agents
Dosage form:	Hard Gelatin Capsules
Composition:	Duloxetine (as delayed release pellets) IP + Pregabalin IP (20mg + 75mg, 20mg + 50mg & 30mg + 75mg) hard gelatin capsules
Indications:	For the treatment of patients with moderate to severe neuropathic pain

Details of clinical trial site:

Names and address of clinical trial site:	As per annexure- A
Ethics committee details:	As per annexure- A
Name of principal investigator:	As per annexure- A

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Vipin Ola	Apex Hospitals Private Limited, SP-4 & 6, Malviya Industrial Area, Near Apex Circle, Malviya Nagar, Jaipur-302017, Rajasthan.	Institutional Ethics Committee, Apex Hospitals Private Limited, SP - 4 and 6, Malviya Industrial Area, Malviya Nagar, Jaipur-302017, Rajasthan. ECR/380/Inst/RJ/2013/RR19
2	Dr. Sanjiv Maheshwari	Department of Medicine, 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
3	Dr. Hrishikesh Bora	Down Town Hospital, Dispur, G.S. Road, Guwahati-781006, Assam.	Ethics Committee, Down Town Hospital, 6th Floor, 1st Building, G.S. Road, Dispur, Guwahati-781006 Assam ECR/549/Inst/AS/2014/RR20
4	Dr. Shankar Ramagouda Patil	Tyzer Clinical Research Pvt. Ltd. at Prakash Institute of Medical Sciences & Research, Urun-Islampur (PIMS&R), Islampur-Sangali Road, Islampur, Tal-Walwa, Dist-Sangali, Maharashtra-415409.	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Research, UrunIslampur (PIMS&R), Islampur-Sangali Road, Islampur, Tal-Walwa, DistSangali, Maharashtra-415409. ECR/1052/Inst/MH/2018
5	Dr. J. Naganna	In Patient Block, 3rd Floor, Department of Medicine, Gandhi Medical College / Hospital, Musheerabad, Secunderabad-500003, Telangana	Institutional Ethics Committee, Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabad500003, Telangana ECR/180/Inst/AP/2013/RR19
6	Dr. S.S.V.V. Narasinga Rao	Department of Medicine, Government Medical College & Government General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh.	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001, Andhra Pradesh. ECR/492/Inst/AP/2013/RR20
7	Dr. Prabhat Kumar Sharma,	Maharaja Agrasen Superspeciality Hospital, Jaipur, Rajasthan.	ECR/1222/Inst/RJ/2019
8	Dr. Mahendra Pal Singh,	GSVM Medical College, Kanpur, Uttar Pradesh.	ECR/680/Inst/UP/2014/RR-20
9	Dr. Raja Bhattacharya	Medical College and Hospital, Kolkata, West Bengal.	ECR/287/Inst/WB/2013/RR-19
10	Dr. Vijaykumar Bhagwan Barge,	Rajarshee Chhatrapati Shahu Maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Kolhapur, Maharashtra.	ECR/703/Inst/MH/2015/RR-20

Place: New Delhi

Date:

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 Dte. General of Health Services
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