

Nil

File No. FDC/MA/21/000026 ✓
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

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

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

10 AUG 2021

To,

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

Subject: Permission to conduct Phase III clinical trial with the FDC of Teneiglipitin Hydrobromide hydrate eq to Teneiglipitin IP + Dapagliflozin propanediol monohydrate eq to Dapagliflozin (20mg + 10mg, 20mg + 5mg) film coated tablets (Vide protocol no. CRPL/CT/21/002, version no. 00, dated: 13.01.2021)-regarding.

Dear Sir,

With reference to your letter No. nil dated 27.01.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-122/2021 under the provision of Drugs and Cosmetics Act and Rules. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully,



(Dr. V. G. Somani)
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:
 - 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 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;

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

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

Permission no.: CT-06-122/2021

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 **CRPL/CT/21/002, version no. 00, dated: 13.01.2021** 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:

Date:

10 AUG 2021

Annexure:

Details of new drug or investigational new drug:

V.K.S.
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, Kotla Road, I.T.O.
New Delhi-110002

Names of the new drug or investigational new drug:	FDC of Teneiglipitin Hydrobromide hydrate eq to Teneiglipitin IP + Dapagliflozin propanediol monohydrate eq to Dapagliflozin film coated tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablet
Composition:	Each film coated tablets contains: Teneiglipitin Hydrobromide hydrate eq to Teneiglipitin IP..... 20mg/20mg Dapagliflozin propanediol monohydrate eq to Dapagliflozin..... 5mg/10mg
Indications:	For the treatment of Patients with Type 2 Diabetes Mellitus Inadequately Controlled on Metformin Monotherapy.

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

Permission no.: CT-06-122/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Saurabh Agarwal	Post Graduate Department of Medicine, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh	Ethics Committee, GSVM Medical College, Room No-125, 1st Floor, Swaroop Nagar, Kanpur-208002, Uttar Pradesh. ECR/680/Inst/UP/2014/RR20.
2	Dr. Vipul Khandelwal	Apex Hospitals Private Limited, SP-4 & 6, Malviya Industrial Area, 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
3	Dr. Prabhat Kumar Sharma	Maharaja Agrasen Superspeciality Hospital, Jaipur, Rajasthan	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan, India. ECR/1222/Inst/RJ/2019
4	Dr. Sanjiv Maheshwar	Department of Medicine, Jawahar Lal Nehru (J.L.N) Medical College, Kala Bagh, Ajmer305001, Rajasthan.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan. ECR/1156/Inst/RJ/2018
5	Dr. Swapnav Borthakur	Down Town Hospital, Dispur, G.S. Road, Guwahati-781006, Assam.	Ethics Committee, Down Town Hospital, 6 th Floor, 1 st Building, G.S. Road, Dispur, Guwahati-781006, Assam. ECR/549/Inst/AS/2014/RR20
6	Dr. Arindam Naskar	Calcutta School of Tropical Medicine, Government of West Bengal, 108, Chittranjan Avenue, Calcutta-700073, West Bengal	Clinical Research Ethics Committee, Department of Clinical and Experimental Pharmacology, Calcutta School of Tropical Medicine, 108, C R Avenue, Kolkata-700073, West Bengal. ECR/194/Inst/WB/2013/RR19
7	Dr. Shankar Ramagouda Patil	Tyzer Clinical Research Pvt. Ltd., 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.
8	Dr. D. Anil Kumar	Department of General 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.

9	Dr. G. Gouri Prasad	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
10	Dr. Vikas Reddy Maddali	Osmania Medical College & General Hospital, Afzalgunj, Hyderabad, Telangana-500012.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana State. ECR/300/Inst/AP/2013/RR19

Place:

Date:

10 AUG 2021

V. G. S.
Central Licencing Authority
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