

Nil

File No. FDC/MA/21/000231  
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:

29 NOV 2021

To,

M/s. Theon Pharmaceuticals Ltd.,  
Village Saini Majra, Tehsil Nalagarh, Distt. Solan,  
Baddi, Himachal Pradesh-174101.

**Subject:** Permission to conduct Phase III clinical trial with the FDC of Teneiglipitin IP + Rosuvastatin Calcium IP (20mg + 5mg, 20mg + 10mg & 20mg + 20mg) tablets (Vide protocol no. SB-IND-CT-019, version no. 1.0, dated: 08.09.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 22.09.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-188/2021 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;
- 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;

FORM CT-06

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

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

Permission no.: CT-06-188/2021

1. The Central Licencing Authority hereby permits **M/s. Theon Pharmaceuticals Ltd., Village Saini Majra, Tehsil Nalagarh, Distt. Solan, Baddi, Himachal Pradesh-174101** (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. SB-IND-CT-019, version no. 1.0, dated: 08.09.2021**) 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: .....

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Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Teneligliptin IP + Rosuvastatin Calcium IP (20mg + 5mg, 20mg + 10mg & 20mg + 20mg) tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Teneligliptin IP + Rosuvastatin Calcium IP (20mg + 5mg, 20mg + 10mg & 20mg + 20mg) tablets
Indications:	In patients suffering from Dyslipidemia associated with Type 2 Diabetes Mellitus.

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

  
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



**Annexure-A**Permission no.: **CT-06-188/2021**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Anandkumar Patel	Anand Multispecialty Hospital, B-Tower Sundervan Complex, Beside IOCL Petrol Pump, Near Gorwa, Vadodara, Gujarat 390016.	Anand Institutional Ethics Committee, B-Tower Sundervan Complex, Beside IOCL Petrol Pump, Near Gorwa, Vadodara, Gujarat 390016. ECR/RENEW/INST/2021/ 10724
2	Dr. Jigar Piyush Modia	Jupiter Hospital Sun Pharma-Atladra Road, Opp ICAI, Bhavan , Atladra., Vadodara, Gujarat- 390012	Anand Institutional Ethics Committee, B- Tower Sundarvan Complex beside IOCL Petrol Pump, Vadodara, Gujarat- 390016, India ECR / 725 / Inst / GJ / 2015 / RR-21
3	Dr. Hiren Patt	Kusum Dhirajlal Hospital, Vaishnodevi Circle, SG Highway, Ahmedabad-382421	KD Hospital Institutional Ethics Committee, Kusum Dhirajlal Hospital, Vaishnodevi Circle, SG Highway, Ta. Dascroi, Dist. Ahmedabad, Gujarat-382421 ECR/1294/Inst/GJ/2019
4	Dr. Sonali Bhojane	Nectar Diabetes & Thyroid Centre, 202, 2 <sup>nd</sup> Floor, Near Laxmi Narayan Theatre, Mitramandal Road, Swargat Pune-411009	IEC of Sai Sneh Hospital & Diagnostic Centre, Opp PMT Bus Dept, Pune-Satara Road, Katraj Pune-411046 CR/989/Inst/MH/2017/RR-20
5	Dr. Karishma Manwani	Gujarat Kidney & Superspecialty Hospital, New India Mill Compound, Near Jetalpur Overbridge, Jetalpur Road, Vadodara, Gujarat-390020	Anand Institutional Ethics Committee, B-Tower Sundervan Complex, Beside IOCL Petrol Pump, Near Gorwa, Vadodara, Gujarat 390016. ECR/RENEW/INST/2021/ 10724
6	Dr. Chandrashekhar S. Gillurkar	Gillurkar Multispecialty Hospital, 20, Reshimbag, Umred Road, Nagpur-440009	Gillurkar Hospital Ethics Committee, 20, Reshimbag, Umred Road, Nagpur-440009 ECR/1374/INST/MH/2020
7	Dr. Durgaprasad Sadhupati,	Help Hospitals Private Limited, D. No. 27-29-23, Behind Victoria Museum, M.G. Road, Governorpet, Vijayawada-520002, Andhra Pradesh, India	Ethics Committee Help Hospitals Private Limited, Help Hospitals Private Limited D. No. 27-29-23, Behind Victoria Museum, M.G. Road, Governorpet, Vijayawada - 520 002, Andhra Pradesh, India ECR/1 356/INST/AP12020

8	Dr. Lolini Roopa Kolli	Sunrise Hospital (A Unit of NS Health Care Service Pvt. Ltd.) Opp. Corporation Bank, Near Pushpa Hotel Centre, Bellapu, Sobhanadri Road, Suryaraopet, Vijayawada-520002, Andhra Pradesh	Institutional Ethics Committee Sunrise Hospitals, Sunrise Hospitals (A Unit of NS Health Care Services Pvt. Ltd., #33-25-35, Opp. Corporation Bank, Near Pushpa Hotel Centre, Vijayawada-520002, Andhra Pradesh ECR/756/INST/AP/2015/RR-21
9	Dr. Manav Vishwanath Pagare	Shraddha Hospital & Critical Care Center, Plot No. 09, Vishal Nagar, Opposite KADA office, Aurangabad-431005	Institutional Ethics Committee, Shraddha Hospital & Critical Care Center, Plot No. 09, Vishal Nagar, Opposite KADA office, Aurangabad-431005 & ECR/1068/Inst/MH/2018/RR-21
10	Dr. Sagar Sudhir Mandlik	Vakratunda Hospital Pvt. Ltd., Raghukul Sankul (Sale Tax Office Road), Behind Hotel Bandhuraj (Mumbai Agra Hiway), Pathardi Phata, Nashik, Maharashtra-422010	Navsanjeevani Hospital Ethics Committee, Plot No. 08, Motkari Nagar, Tidke Colony, Nashik-422002 ECR/1036/Inst/2021/11453

Place: New Delhi

Date: .....

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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.  
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