

Nil

File No. FDC/MA/21/000210  
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:

25 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 Nortriptyline IP 10mg + Methylcobalamin IP 1500mcg + Pregabalin IP (SR) 75mg tablets (Vide protocol no. SB-IND-CT-018, version no. 1.0, Amendment 1.0 dated: 28.09.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 27.08.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-174/2021 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:
  - iii. 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;
  - iv. 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 Licencing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same site;

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-06-174/2021

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-018, version no. 1.0, Amendment 1.0 dated: 28.09.2021**) 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:	Nortriptyline IP 10mg + Methylcobalamin IP 1500mcg + Pregabalin IP (SR) 75mg tablets
Therapeutic class:	Analgesic
Dosage form:	Tablets
Composition:	Nortriptyline IP 10mg + Methylcobalamin IP 1500mcg + Pregabalin IP (SR) 75mg tablets
Indications:	<b>It is used in the treatment of neuropathic pain with coexistent Vitamin B12 Deficiency</b>

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



Permission no.: CT-06-174/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Durgaprasad Sadhupati, MBBS, M.D (General Medicine)	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
2	Dr. Abhijit Rajendra Sonawane	NAMCO Charitable Trust's S.S.G.S. Cancer Hospital. Plot No. 30III1BI1 & 30I2I2CI2. Opp. R.T.O. Office. Sardar Vallabh Bhai Patel Marg. Peth Road. Panchavati. Nashik-422004. Maharashtra, India	NAMCO Hospital Ethics Committee, C/o NAMCO Charitable-Trust's Multispecialty Hospital, Opp. RTO Office, Sardar Vallabh Bhai Patel Road. Peth Road. Panchvati. Nashik-422004. Maharashtra. ECR/1281/Inst/MH/2019
3	Dr. Abhishek Patil, Consultant Neurosurgery/Assistant Professor	KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi-590010	Institutional Ethics Committee EC Address KI.ES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belagavi ECR/211/Inst/KAV/2013/RR-19
4	Dr. Amit Bhalchandra Yeole	Chopda Medicare & Research Centre Pvt. Ltd. Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B.H, Vidyalaya, Canada Corner, Nashik-422005, Maharashtra	Magna-Care Ethics Committee, Chopda Medicare & Research Centre Pvt. Ltd. Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B.H, Vidyalaya, Canada Corner, Nashik-422005, Maharashtra ECR/79/Inst/MH/2013/RR-19
5	Dr. Mohan Magdum	Poona Hospital and Research Centre, 27, Sadashiv Peth, Near Alka talkies Pune-411030	Ethics Committee, Poona Hospital and Research Centre, 27, Sadashiv Peth, Near Alka talkies Pune-411030 ECR/327/Inst/MH/2013/RR-19
6	Dr. Man Mohan Mehndiratta	Dr. B.L. Kapur Memorial Hospital, 1st Floor, OPD-8, Centre for Neurosciences, Dept of Neurology, Pusa Road, New Delhi-110005	Dr. B.L. Kapur Memorial Hospital Ethics Committee, Academic Hospital Affairs Research and Continuing Education, Pusa Road, New Delhi-110005 ECR/3/BLK/Inst/DL/2013/RR-19
7	Dr. (Ms) Bhitkar Harshal Narendra	B.J. Govt. Medical College & Sassoon General Hospital, Near Pune Railway Station, Pune-411001.	Institutional Ethics Committee of B.J. Govt. Medical College & Sassoon General Hospital, Near Pune Railway Station, Pune-411001. ECR/280/INST/Maha/2013/RR-19

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
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**Place: New Delhi**

**Date: .....**

25 NOV 2021

*V. G. Somani*

**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, Kotta Road, I.T.O.  
New Delhi-110002