

Nil

File No. FDC/MA/21/000009
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:

To,

M/s. Mascot Health Series Pvt. Ltd.,
Plot No. 79-80, Sector 6A, IIE SIDCUL,
Haridwar, Uttarakhand-249403.

07 DEC 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Metoprolol Succinate IP (ER) 50mg + Azelnidipine IP 16mg film coated bilayered tablets (Vide protocol no. MCR/CT/0820/04, version no. 01, dated: 13.09.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 24.02.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-191/2021** 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;

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-06-191/2021**

1. The Central Licencing Authority hereby permits **M/s. Mascot Health Series Pvt. Ltd., Plot No. 79-80, Sector 6A, IIE SIDCUL, Haridwar, Uttarakhand-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. MCR/CT/0820/04, version no. 01, dated: 13.09.2021** 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:.....

07 DEC 2021

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Metoprolol Succinate IP (ER) 50mg + Azelnidipine IP 16mg film coated bilayered tablets
Therapeutic class:	Antihypertensive
Dosage form:	Tablets
Composition:	Metoprolol Succinate IP (ER) 50mg + Azelnidipine IP 16mg film coated bilayered tablets
Indications:	For the treatment of stage 2 hypertension

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

डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एन.जी.ए. भवन, कोटला रोड, आई.टी.डी.
नई दिल्ली-110002

Permission no.: CT-06-191/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr Nikhil Jadhav	Asian Institute of Medical Sciences, P-72, Milap Nagar, MIDC, Dombivli (East)- 421203, Maharashtra, India	Suraksha Ethics Committee, Asian Institute of Medical Sciences, P-72, Milap Nagar, MIDC, Dombivli (East)- 421203, Maharashtra, India ECR/644/Inst/MH /2014/RR-17
2	Dr Deshpande Shrikant Vishnu	Ashirvad Hospital and Research Centre, Maratha Section, Near Jijamata Udyan, Ulhasnagar, Thane-421004, Maharashtra, India	Ashirvad Ethics Committee, Ashirvad Hospital and Research Centre, Maratha Section, Near Jijamata Udyan, Ulhasnagar, Thane-421004, Maharashtra, India ECR/247/Inst/MH /2013/RR-19
3	Dr Krishna Madhukar Giri	Dhadiwal Hospital In Coalition with Shreeji Healthcare, Opp. New CBS, Trimbak Road, Nashik- 422002, Maharashtra, India.	Shree Institutional Ethics committee, Dhadiwal Hospital In Coalition with Shreeji Healthcare, Opp. New CBS, Trimbak Road, Nashik- 422002, Maharashtra, India. ECR/1149/Inst/M H/2018
4	Dr Vijaykumar Patil	Tyzer Clinical Research Pvt. Ltd. At Prakash Institute of Medical Research, Urun, Islampur, tal-Walwa, Dist Sangli, 415409, Maharashtra, India	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Research, Urun, Islampur, tal-Walwa, Dist Sangli, 415409, Maharashtra, India ECR/1052/Inst/M H/2018
5	Dr. Mahendra Pal Singh	Post Graduate Department of Medicine, GSVM Medical College, Kanpur-208002, UP, India	Ethics Committee, GSVM Medical College, Room no 125 1st Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Up, India ECR/680/Inst/UP/2 014/RR-20

Place:

Date:

07 DEC 2021


Central Licencing Authority
Stamp

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 ए.जी.ए. भवन, कोटला रोड, आई.टी.ओ
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