

Nil

File No. FDC/MA/20/000151 ✓
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:

21 SEP 2021

To,

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

Subject: Permission to conduct Phase III clinical trial with the FDC of Azelnidipine 16mg + Telmisartan IP 40mg tablets (Vide protocol no. MCR/CT/0221/01, version no. 01, dated: 23.06.2021)-regarding.

Dear Sir,

With reference to your online application submitted in CT-21 on dated 12.10.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-155/2021** 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-06-155/2021**

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/0221/01, version no. 01, dated: 23.06.2021**) 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:

21 SEP 2021

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Azelnidipine 16mg + Telmisartan IP 40mg uncoated bilayered tablets
Therapeutic class:	Antihypertensive
Dosage form:	Tablets
Composition:	Azelnidipine 16mg + Telmisartan IP 40mg uncoated bilayered tablets
Indications:	For the treatment of stage-II 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

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-06-155/2021

S.No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Krishna Giri	Dhadiwal Hospital in coalition with Shreeji Healthcare, Opp. New CBS, Trimbak road, Nashik- 422002, Maharashtra	Shree Institutional Ethics Committee, Dhadiwal Hospital in coalition with Shreeji Healthcare, Nashik- 422002, Maharashtra ECR/1149/Inst/MH/2018
2	Dr. Nikhil Jadhav	Asian Institute of Medical Sciences, Milap Nagar, MIDC, Dombivli (E)- 421203, Maharashtra	Suraksha Ethics Committee, Asian Institute of Medical Sciences, Dombivli (E)- 421203, Maharashtra
3	Dr. Mahendra Pal Singh	GSVM Medical College, Kanpur- 208002, UP, India	Ethics Committee, GSVM Medical College, Kanpur- 208002, Uttar Pradesh ECR/680/Inst/UP/2014/RR-17
4	Dr. Vijaykumar S. Patil	CROM Clinical Research & Medical Tourism Pvt. Ltd., Prakash Institute of Medical Science & Research, Urun-Islampur (PIMS&R), Sangli- 415409,	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Science & Research, Urun-Islampur (PIMS&R) Sangli- 415409, Maharashtra ECR/902/Inst/GA/2018
5	Dr. Sunil Naik	Government Medical College and Govt. General Hospital, Srikakulam- 532001, Andhra Pradesh, India	Institutional Ethics Committee, Government Medical College and Govt. General Hospital, Srikakulam- 532001, Andhra Pradesh, India ECR/492/Inst/AP/2013/RR-20
6	Dr. Shrikant Vishnu Deshpande	Ashirwad Hospital and Research Centre, Near Jijamata Udyan, Maratha Section, Ulhasnagar- 421004, Maharashtra	Ashirwad Ethics Committee, Ashirwad Hospital and Research Centre, Ulhasnagar- 421004, Maharashtra ECR/247/Inst/MH/2013/ RR-19
7	Dr. Dnyaneshwar Halnor	Vijay Vallabh Hospital and Medical Research Centre, Virar, Maharashtra	Institutional Ethics Committee, Virar (W), Palgarh- 401303, Maharashtra ECR/880/Inst/MH/2017/RR-20
8	Dr. Dharmendra Jain	Banaras Hindu University, Varanasi- 221005, Uttar Pradesh India	Institutional Ethics Committee, Institute of Medical Sciences Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh ECR/526/Inst/UP/20 14/RR-20
9	Dr. Rajeev Garg	Aware Gleneagles Global Hospital, Sagar Road, LB Nagar, Hyderabad - 500 035, Telangana	Institutional Ethics Committee Gleneagles Global Hospitals, Global Good Life Building, Telangana, India
10	Dr. Swapnav Borthakur	Down Town Hospital, Dispur, Guwahati	Ethics Committee, Down Town Hospital, Dispur, Guwahati ECR/549/Inst/AS/2014/RR-20

Place: New Delhi

Date:

21 SEP 2021

Central Licencing Authority

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