

Nil

File No.FDC/MA/21/000187
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No.:011-23236965
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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.

25 NOV 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin 5mg + Vildagliptin 50mg tablets (Vide protocol no. MCR/CT/0721/01, version no. 02, dated: 13.09.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 10.08.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-187/2021** 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;

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

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG****Permission no.: CT-06-187/2021**

1. The Central Licencing Authority hereby permits **M/s. Mascot Health Series Pvt. Ltd., Plot No. 79-80, Sector 6A, IIE SIDCUL, Haridwar, Uttarakhand** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. MCR/CT/0721/01, version no. 02, 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:****25 NOV 2021****Annexure:****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

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Dapagliflozin 5mg + Vildagliptin 50mg tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Dapagliflozin 5mg + Vildagliptin 50mg tablets
Indications:	Management of Type-2 Diabetes mellitus (T2DM)

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-06-187/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Amol Dange	Lifepoint Multispeciality Hospital, No. 145, Sr, 1, Mumbai Pune Bypass Rd, near Sayaji Hotel, Wakad, Pune, Maharashtra 411057.	Lifepoint Multispeciality Hospital Pvt. ltd Near Hotel Sayaji Wakad Pune Maharashtra ECR/751/Inst/ MH/2015/RR18
2	Dr. B. Vivekanand	King George Hospital, Department of Endocrinology, Superspeciality Block, King George Hospital, Maharanipeta, Vishakhapatnam 530002, Andhra Pradesh.	IEC King George hospital King George Hospital Maharanipeta Collector Office junction Visakhapatnam Andhra Pradesh ECR/197/Inst/ KGH/2013/R R-20
3	Dr. Prabhat Kumar Sharma	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidhyadhar Nagar, Jaipur, Rajasthan 302039.	IEC Maharaja Agrasen Hospital Maharaja Agrasen Superspeciality Hospital Central Spine, Agrasen Aspatal Marg, Sector -7 Vidyadhar Nagar, Jaipur, Rajasthan - 302039 ECR/1222/Inst/ RJ/2019
4	Dr. Sunil Naik	Rajiv Gandhi Institute Of Medical Sciences, Shanti Nagar Colony, Balaga, Srikakulam, Andhra Pradesh 532001	Institutional Ethics Committee, Govt. Medical College Govt. General Hospital Balaga Srikakulam Srikakulam Andhra Pradesh ECR/492/Inst/ AP/2013/RR20
5	Dr. Narasinga Rao	Government Medical College & Government General Hospital, Srikakulam-532001	Institutional Ethics Committee Government Medical College & Government General Hospital, Srikakulam-532001 ECR/492/Inst/A P/2013/RR-20
6	Dr. Raja Bhattacharyya	Government medical college and hospital, Kolkata- 700073	Institutional Ethics Committee for Human Research Medical College and Hospital, Kolkata 700073, India ECR/287/Inst/W B/2013/RR-19

Place: New Delhi

Date:

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Central Licencing Authority

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Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
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