

Nil

File No. FDC/MA/22/000017

Tele. No. : 011-23236965

Government of India

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Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

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.

28 JUN 2022

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin IP 10mg + Metformin Hydrochloride IP (as sustained release) 1000mg + Sitagliptin Phosphate Monohydrate IP 100mg bilayered tablet (Vide protocol no. MCR/CT/0122/03, version no. 01, dated 29.03.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 21.01.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-36/2022** 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.: **FDC-CT-06-36/2022**

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, Telephone no. 01334-239039, Fax no. 01334-239039** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. MCR/CT/0122/03, version no. 01, dated 29.03.2022**) 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:

28 JUN 2022

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Dapagliflozin IP 10mg + Metformin Hydrochloride IP (as sustained release) 1000mg + Sitagliptin Phosphate Monohydrate IP 100mg bilayered tablet
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Each bilayered tablet contains: Dapagliflozin IP 10mg Metformin Hydrochloride IP 1000mg (as sustained release) Sitagliptin Phosphate Monohydrate IP 100mg
Indications:	It is indicated as an adjunct to diet and exercise to improve glycaemic control in adults 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
डॉ. ए. पी. साहनी
जीएचसी (भारत)
पंजीकृत चिकित्सक

Annexure-A**Permission no.: FDC-CT-06-36/2022**

S.No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Prabhat Kumar Sharma	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur, Rajashthan-302039	IEC Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, Jaipur, Rajashthan-302039 ECR/1222/Inst/RJ/2019
2	Dr. Richa Giri	GSVM Medical College, Post Graduate Department of Medicine, GSVM Medical college, Swaroop Nagar, Kanpur-208002, UP	Ethics Committee GSVM Medical College Kanpur Swaroop Nagar Kanpur Nagar, Uttar Pradesh ECR/680/Inst/UP/2014/RR-2020
3	Dr. Sahana Shetty	Kasturba Medical College & Hospital, MAHE, Manipal-576104, Karnataka, India	MAHE Ethics Committee, MAHE, Manipal-576104, Karnataka ECR/191/Inst/ KL/2013/RR-19
4	Dr. Shantanu Sengupta	Sengupta Hospital and Research Institute Ravi Nagar Square, Amravti Road, Nagpur-440033	Sengupta Hospital and Research Institute Ethics Committee, Sengupta Hospital and Research Institute Ravi Nagar Square, Amravti Road, Nagpur-440033 ECR/675/Inst/MH/2014/RR-20
5	Dr. K. Sunil Naik	Government Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh	Institutional Ethics Committee, Government Medical College & Govt. General Hospital Srikakulam-532001, Andhra Pradesh. ECR/492/Inst/ AP/2013/RR20

Place: New Delhi**Date:****28 JUN 2022****Central Licencing Authority****Stamp**

डॉ. पी. जी. जोशी
 अध्यक्ष, नैतिकता समिति (नगर)
 सेंट्रल लिसेंसिंग प्राधिकरण