Nil

File No. FDC/MA/22/000083

Tele. No. : 011-23236965
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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

FDA Bhawan, Kotla Road
New Delhi-110002

Dated: 24 JUN 2022

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 Metformin Hydrochloride IP (SR) + Pioglitazone Hydrochloride IP + Sitagliptin Phosphate IP eq. to Sitagliptin (500mg + 15mg + 100mg & 1000mg + 15mg + 100mg) film coated bilayered tablet (Vide protocol no. MCR/CT/0122/02, version no. 01, dated 19.05.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 21.03.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-52/2022** 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-06-52/2022

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/0122/02, version no. 01, dated 19.05.2022)** 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: 24 JUN 2022

Central Licencing Authority

Stamp

डॉ. जी. जी. योगानी
औषधि महानियंत्रक (भारत)
केन्द्रीय औषधि मानक नियंत्रण संगठन

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Metformin Hydrochloride IP (SR) + Pioglitazone Hydrochloride IP + Sitagliptin Phosphate IP eq. to Sitagliptin (500mg + 15mg + 100mg & 1000mg + 15mg + 100mg) film coated bilayered tablet
Therapeutic class:	Antidiabetic
Dosage form:	Film Coated Bilayered Tablet
Composition:	Each film coated bilayered tablet contains: Metformin Hydrochloride IP (SR) + Pioglitazone Hydrochloride IP + Sitagliptin Phosphate IP eq. to Sitagliptin (500mg + 15mg + 100mg & 1000mg + 15mg + 100mg)
Indications:	Patients 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

Annexure-A

Permission no.: FDC-CT-06-52/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. B. Vivekanand	King George Hospital, Department of Endocrinology, Superspeciality Block, King George Hospital, Maharanipeta, Vishakhapatanam-530002, Andhra Pradesh, India.	IEC King George Hospital, Maharanipeta Collectors Office Junction Visakhapatnam Andhra Pradesh-530002. ECR/197/Inst/ KGH/2013/RR-20
2	Dr. Raja Bhattacharyya	Medical College and Hospital, Kolkata 88 College Street Kolkata-700073, West Bengal, India.	Institutional Ethics Committee for Human Research Medical Colleg and Hospital Kolkata, 88, College Street, Kolkata-700073, India ECR/287/Inst/ WB/2013/RR-19
3	Dr. Richa Giri	Post Graduate Department of Medicine, GSVM Medical college, Swaroop Nagar, Kanpur-208002, UP, India.	Ethics Committee GSVM Medical College, Room No. 125 1 st Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh, India ECR/680/Inst/ UP/2014/RR-20
4	Dr. Shantanu Sengupta	Sengupta Hospital & Research Institute, Ravi Nagar Square, Amravti Road, Nagpur-440033, Maharashtra.	Sengupta Hospital and Research Institute, Ravi Nagar Square, Amravti Road, Nagpur-440033, Maharashtra ECR/675/Inst/ MH/2014/RR-20
5	Dr. Sunil Naik	Government Medical College and Govt. General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh, India.	Institutional Ethics Committee, Government Medical College and Govt. General Hospital Srikakulam532001, Andhra Pradesh, India. ECR/492/Inst/ AP/2013/RR-20
6	Dr. Sahana Shetty	Department of Endocrinology, Kasturba Medical College, Manipal Academy of Higher Education, Madhav Nagar, Manipal-576104, Karnataka, India	Manipal Academy of Higher Education Ethics Committee Madhav Nagar, Manipal-576104, Karnataka, India ECR/191/Inst/ KL/2013/RR-19

Place: New Delhi

Date: .....

24 JUN 2022

Central Licencing Authority

Stamp