Nil

File No. FDC/MA/20/000142

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:

19 AUG 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 Vildagliptin SR 100mg + Metformin Hydrochloride (SR) IP 1000mg uncoated bilayered tablets (Vide protocol no. MCR/CT/0121/02, version no. 00, dated: 21.01.2021)- regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 10.10.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-24/2021** 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;

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-06-24/2021

1. The Central Licencing Authority hereby permits **M/s. Mascot Health Series Pvt. Ltd.,**
2. **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/0121/02, version no. 00, dated: 21.01.2021** in the below mentioned clinical trial sites.
3. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
4. 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: 19 AUG 2021

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

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Vildagliptin SR 100mg + Metformin Hydrochloride (SR) IP 1000mg uncoated bilayered tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Vildagliptin SR 100mg + Metformin Hydrochloride (SR) IP 1000mg uncoated bilayered tablets
Indications:	For the treatment of type-II diabetes mellitus when single drug therapy alongwith diet, exercise do not result in adequate glycemic control

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.: CT-06-24/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Sunil M. Jain	BCM Health Island, PU4 Scheme 54, Behind Prestige Management Institute, Near Bombay Hospital, Indore – 452010, MP, India	EC of Diabetes Thyroid Research Institute, Scheme 54, Behind Prestige Management Institude, Near Bombay Hospital, Indore – 452010, MP, India ECR/409/Inst/MP/2013/RR-19
2	Dr. Rich Giri	Post Graduate Department of Medicine, GSVM Medical College, Kanpur-208002, UP, India	Ethics Committee, GSVM Medical College, Kanpur-208002, UP, India ECR/680/ Inst/UP/2014/ RR- 2020
3	Dr, Raja Bhattacharya	Medical College, Kolkata 88, College Street, Kolkata – 700073, West Bengal, India.	Institutional Ethics Committee for Human Research Medical College, Kolkata Medical College, Kolkata 88, College Street Kolkata West Bengal-700073, India ECR/287/Inst/WB/2013/RR-19
4	Dr. Avinash Kumbhar	Aster Aadhar Hospital (Prerana Hospital Ltd), R.S. No. 628, B Ward, Near Shastri Nagar, Kolhapur, Maharashtra- 416012, India	Aster Aadhar Ethics Committee , Aster Aadhar Hospital R.S. No. 628, B Ward Near Shastri Nagar KMT Workshop Kolhapur Kolhapur, Maharashtra - 416012 ECR/470/Inst/MH/2013/RR-19
5	Dr. Krishna Giri	Dhadiwal Hospital In Coalition with Shreeji Healthcare, Nasik 422002	Shree Institutional Ethics Committee, Opp. New CBS Trimbak Road, Nashik-422002 ECR/1149/Inst/MH/2018
6	Dr Brij Mohan Goyal	Apex Hospital Pvt. Ltd, SP 4 & 6, MIA, Malviya Nagar, Jaipur-302017, Rajasthan	Institutional Ethics Committee, Apex Hospital Private Limited
7	Dr Kumar Gouraba Behera	Institute of Medical Sciences (IMS) and SUM Hospital, S'O'A University, K8, Kalinga Nagar, Bhubaneswar-751003, Odisha, India. Cuttack, Orissa	IEC IMS and SUM Hospital K-8 , Kalinganagar Shampur Bhubaneswar Khordha Odisha-751003, India ECR/627/Inst/OR/2014/RR-20

Place: New Delhi

Date: .....

19 AUG 2021

Central Licencing Authority
Dr. V. G. SOMANI
Drugs Controller General (India)
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