

Nil

File No. FDC/MA/22/000036 ✓

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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:

To,

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

27 MAY 2022


Subject: Permission to conduct Phase III clinical trial with the FDC of Vildagliptin (SR) + Pioglitazone Hydrochloride IP (100mg + 15mg & 100mg + 30mg) film coated bilayered tablets (Vide protocol no. MCR/CT/0122/04, version no. 01, dated 13.04.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 09.02.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-48/2022** 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 Licencing 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 DRUGPermission no.: **FDC-CT-06-48/2022**

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/0122/04, version no. 01, dated 13.04.2022**) 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:

27 MAY 2022

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Vildagliptin (Sustained Release) + Pioglitazone Hydrochloride IP (100mg + 15mg & 100mg + 30mg) film coated bilayered tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Each film coated bilayered tablets contains: 1. Vildagliptin (SR) 100mg Pioglitazone Hydrochloride IP 15mg 2. Vildagliptin (SR) 100mg Pioglitazone Hydrochloride IP 30mg
Indications:	For the treatment of Type II 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. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
एफ.डी.ए. भवन, कोटला रोड़, आई.टी.ओ.
नई दिल्ली-110002

Annexure-A

Permission no.: FDC-CT-06-48/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Richa Giri	Post Graduate Department of Medicine, GSVM Medical College, Kanpur-208002, UP	Ethics Committee GSVM Medical College, Room no. 125, 1 st Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh ECR/680/Inst/ UP/2014/RR20
2	Dr. B. Vivekanand	Andhra Medical College/King George Hospital, Department of Endocrinology, Superspeciality Block, Maharanipecta, Vishakhapatnam-530002, Andhra Pradesh	IEC King George Hospital, King George Hospital, Maharanipecta Collector office junction, Visakhapatnam, Andhra Pradesh, 532002 ECR/197/Inst/ KGH/2013/R R-20
3	Dr. Veer Bahadur Singh	JLN Medical College, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh Ajmer-305001, Rajasthan ECR/1156/Inst/RJ/2018
4	Dr. Shantanu Sengupta	Sengupta Hospital and Research Institute Ravi Nagar Square, Amravti Road, Nagpur-440033	Sengupta Hospital and Research Institute Ethics Committee, Ravi Nagar Square, Amravti Road, Nagpur-440033 ECR/675/Inst/MH/2014/RR-20
5	Dr. Sahana Shetty	Kasturba Medical College and Hospital, MAHE, Manipal-576104, karnataka, India	MAHE Ethics Committee, MAHE, Manipal-576104, Karnataka ECR/191/Inst/ KL/2013/RR-19

Place: New Delhi

Date:

27 MAY 2022


Central Licencing Authority

Stamp

डॉ. वी. जी. सोमानी

औषधि महानियंत्रक (भारत)

स्वास्थ्य सेवा महानिदेशालय

संलग्न एवं परिवार कल्याण मंत्रालय

पुस्तक भवन, पुराना सिड, आई.टी.ओ.

पिन-110002