Nil

File No. FDC/MA/21/000235
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:

04 AUG 2022

To,

M/s. Pure & Cure Healthcare Pvt. Ltd.,
Plot No. 26A, 27-30, Sector-8A, IIE, SIDUCL,
Ranipur, Haridwar, Uttrakhand-249403.

Subject: **Permission to conduct Phase III clinical trial with the FDC of Vildagliptin (as sustained release form) + Metformin Hydrochloride (as sustained release form) IP (50mg + 500mg & 50mg + 1000mg) uncoated bilayered tablets (Vide protocol no. BRPL/CT/FDC/VILMF/09/21, version no. 2.0, dated 06.01.2022)- regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 27.09.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-60/2022** 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;

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-06-60/2022

1. The Central Licencing Authority hereby permits **M/s. Pure & Cure Healthcare Pvt. Ltd., Plot No. 26A, 27-30, Sector-8A, IIE, SIDUCL, Ranipur, Haridwar, Uttrakhand-249403, Telephone no. 01334-234327, Fax no. 01334-239219** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. BRPL/CT/FDC/VILMF/09/21, version no. 2.0, dated 06.01.2022)** 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: 04 AUG 2022

Central Licencing Authority

Stamp

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Vildagliptin (as sustained release form) + Metformin Hydrochloride (as sustained release form) IP (50mg + 500mg & 50mg + 1000mg) uncoated bilayered tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Each uncoated bilayered tablets contains: Vildagliptin (as sustained release form) + Metformin Hydrochloride (as sustained release form) IP (50mg + 500mg & 50mg + 1000mg)
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.: FDC-CT-06-60/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Raghavendra S K	Clinical Trial Centre, Adhichunchanagiri Hospital and Research Centre, B G Nagara, Nagamangla Taluk, Mandya, Karnataka-571448	Institutional Ethics Committee Adhichunchanagiri Hospital and Research Centre, B G Nagara, Nagamangla Taluk, Mandya, Karnataka-571448 ECR/1456/Inst/KA/2020
2	Dr. Debananda Sahoo	All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar-751019, Odisha, India	Institutional Ethics Committee All India Institute of Medical Scicnces, Sijua, Patrapada, Bhubaneswar-751019, Odisha, India ECR/534/Inst/OD/2014/RR-20
3	Dr. Abhishek Pande	AXON Multispeciality hospital, Rukhmini complex, near mascott honda,bansi nagar, hingna wadi t point, Nagpur, Maharashtra, India-440028.	AXON Multispeciality Hospital, Rukhmini complex, near mascott honda, bansi nagar, hingna wadi t point, Nagpur, Maharashtra, India 440028. ECR/1558/Inst/MH/2021
4	Dr. Surendra Kumar	S.P Medical College & A.G of Hospital Bikaner (Rajasthan)	Ethics Committee, S.P. Medical College & A.G. of Hospital Bikaner ECR/27/SP/Inst/RJ/2013/RR-19

Place: New Delhi

Date: .....

01 AUG 2022

Central Licencing Authority

Stamp