2217/16.03.22

File No. FDC/MA/20/000099

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: 06 JUL 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 IV clinical trial with the FDC of Mirabegron (ER) + Solifenacin Succinate IP (25mg + 5mg & 50mg + 5mg) film coated bilayered tablet (Vide protocol no. BRPL/CT/FDC/MISOL/10/21, version no. 1.0, dated 22.10.2021)-regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 21.07.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-56/2022** 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,

VL

(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-06-56/2022

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** (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. BRPL/CT/FDC/MISOL/10/21, version no. 1.0, dated 22.10.2021)** 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: 06 JUL 2022

Central Licencing Authority

Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Service
Ministry of Health and Family We
DA Bhawan, Kotla Road, I.T.C
New Delhi-110002

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Mirabegron (ER) + Solifenacin Succinate IP (25mg + 5mg & 50mg + 5mg) film coated bilayered tablet
Therapeutic class:	Muscarnic Antagonist Drug
Dosage form:	Tablets
Composition:	Each film coated bilayered tablet contains: Mirabegron (ER) + Solifenacin Succinate IP (25mg + 5mg & 50mg + 5mg)
Indications:	In adult patients with symptoms of overactive bladder

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-06-56/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Partha Protim Mondal	GMC, Kolkata, Department of Urology, Medical College and Hospital, Kolkata 88, College Street, Kolkata 700073, West Bengal, India	Institutional Ethics Committee for Human Research Medical College and Hospital, Kolkata, 88, College Street Kolkata - 700073, West Bengal, India ECR/287/Inst/WB/2013/RR-19
2	Dr. Vinay Kumar	GSVM Medical College, Swaroop Nagar, Kanpur - 208002	Ethics Committee, GSVM Medical College, Room no:125, 1st floor, Swaroop Nagar, Kanpur - 208002 ECR/680/INST/UP/2014/RR-20
3	Dr. Dilip Kumar Pal	IPGMER & SSKM Hospital, Department of nephrology, 244 AJC Bose Road, Kolkata - 700020, West Bengal, India	IPGME & R Oversight Committee Institute of Post Graduate Medical Education and Research, 244 AJC Bose Road, Kolkata - 700020, West Bengal ,India. ECR/35/Inst/WB/2013/RR-19
4	Dr. Ravindra Deshmukh	Jasleen Hospital, Kidney Centre, 1st floor, Panchasheel square, Wardha Road, Nagpur-440012, Maharashtra, India	Jasleen Hospital Ethics Committee, Opp.Big Bazar, Panchasheel square, Dhantoli, Nagpur-440012, Maharashtra, India ECR/264/Inst/MH/2013/RR-20
5	Dr. Narasimhaswamy P.	MIMS, Mandya, Dist. Hospital Campus, Pin Code - 571401	Institutional Ethics Committee, MIMS, Mandya Mandya MC Road, Nehrunagar, Mandya, Karnataka - 571401, India. ECR/405/Inst/KA/2013/RR-21

Place: New Delhi

Date: .....

06 JUL 2022

Central Licencing Authority

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. Gen... Services
Ministry of ... Family Welfare
... I.I.O.

Stamp