

Nil

File No. FDC/MA/21/000254
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Tele. No. : 011-23236965
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FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

16 DEC 2021

To,
M/s. Windlas Biotech Ltd.,
Khasra No. 141 to 143 & 145,
Mohabewala Industrial Area,
Dehradun-248110, Uttarakhand.

Subject: Permission to conduct Phase III clinical trial with the FDC of Mirabegron (As extended release) + Silodosin (25mg + 8mg & 50mg + 8mg) film coated bilayered tablets (Vide protocol no. SIME/WBL/P3/2021, version no. 1.0, dated: 22.09.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 22.10.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-200/2021 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;
- 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.: CT-06-200/2021

1. The Central Licencing Authority hereby permits M/s. Windlas Biotech Ltd., Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun-248110, Uttarakhand to conduct clinical trial of the new drug or investigational new drug as per protocol number (Vide protocol no. SIME/WBL/P3/2021, version no. 1.0, dated: 22.09.2021 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: 15 DEC 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:	Mirabegron (As extended release) + Silodosin (25mg + 8mg & 50mg + 8mg) film coated bilayered tablets
Therapeutic class:	Urology
Dosage form:	Tablets
Composition:	Each Film coated bilayered tablets contains: Mirabegron (As extended release) + Silodosin (25mg + 8mg & 50mg + 8mg)
Indications:	In adult patients diagnosed with Benign Prostatic Hyperplasia complicated by overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and frequency.

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-06-200/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Rajiv Chander	Gandhi Hospital, 5th floor, Department of Urology, Gandhi Hospital, Musheerabad, Secunderabad, Telangana-500003.	Institutional Ethics Committee, Gandhi Medical / Hospital College, Musheerabad, Secunderabad, Telangana-500003 ECR/180/Inst/AP/2013/RR-19
2	Dr. Ranjan Kumar Dey	Life Line Diagnostic Centre cum Nursing Home, 4A, Wood Street, Kolkata-700016, West Bengal	Institutional Ethics Committee, Life Line Diagnostic Centre cum Nursing Home, 4A, Wood street, Kolkata-700016, West Bengal ECR/1334/Inst/WB/2020
3	Dr. Sudheer Khanna	Sir Gangaram Hospital, Sir Gangaram Hospital Marg, Rajinder Nagar, New Delhi-110060	Sir Gangaram Hospital Ethics Committee, Sir gangaram Hospital Marg, Old Rajinder Nagar, New Delhi-110060 ECR/20/Inst/DL/2013/RR-19
4	Dr. Vasim M Mulla	Asian Multispecialty Hospital, Near Titan Showroom, Behind Canara Bank, Dasara Chowk, Kolhapur-416004, Maharashtra	Shreyas Hospital Institutional Ethics committee, Shreyas Hospital, 6th line, Rajarampuri, Kolhapur, Maharashtra -416008 ECR/962/Inst/MH/2017/RR-20

Place: New Delhi

Date:

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