Nil

File No. FDC/MA/22/000042

Tele. No. : 011-23236965
Fax No. : 011-23236973

**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. Windlas Biotech Ltd. (Plant-2),**
**Khasra No. 141 to 143 & 145,**
**Mohabewala Industrial Area,**
**Dehradun-248110, Uttrakhand.**

16 JUN 2022

**Subject: Permission to conduct Phase III clinical trial with the FDC of Vildagliptin 50mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg uncoated tablets (Vide protocol no. SB-IND-CT-027, version no. 1.0, dated 16.11.2021, Amendment 01, dated 18.04.2022)-regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 12.02.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-51/2022** 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 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.: FDC-CT-06-51/2022**

1. The Central Licencing Authority hereby permits **M/s. Windlas Biotech Ltd. (Plant-2), Khasra No. 141 to 143 & 145, Mohabewala Industrial Area, Dehradun-248110, Uttrakhand, Telephone no. 0135-6608000, Fax: 0135-6608199, email: regaffairs@windlas.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. SB-IND-CT-027, version no. 1.0, dated 16.11.2021, Amendment 01, dated 18.04.2022)** 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: .....**
15 JUN 2022

**Central Licencing Authority**

**Stamp**

डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
नई दिल्ली-110002

**Annexure:**

**Details of new drug or investigational new drug:**

| | |
|---|---|
| **Names of the new drug or investigational new drug:** | Vildagliptin 50mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg uncoated tablets |
| **Therapeutic class:** | Antidiabetic |
| **Dosage form:** | Tablets |
| **Composition:** | Each uncoated tablets contains:<br>Vildagliptin .... 50mg<br>Pioglitazone Hydrochloride IP<br>Eq. to Pioglitazone .... 15mg |
| **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 |

**Annexure-A**

**Permission no.: FDC-CT-06-51/2022**

| S. No. | Name of PI | Site Name | Ethics Committee Name, Address & EC registration No. |
|---|---|---|---|
| 1 | Dr. Manav Vishwanath Pagare | Shraddha Hospital & Critical Care Center, Plot No. 09, Vishal Nagar, Opposite KADA office, Aurangabad-431005 | Institutional Ethics Committee, Shraddha Hospital & Critical Care Center, Plot No. 09, Vishal Nagar, Opposite KADA office, Aurangabad-431005 ECR/1068/Inst/MH/2018/RR-21 |
| 2 | Dr. Ajay Kumar Ajmani | Dr. B.L. Kapur Memorial Hospital Address: Pusa road, New Delhi-10005, India | Dr. B.L. Kapur Memorial Hospital Ethics Committee EC Address: Dr. B.L. Kapur Memorial Hospital Academic Affairs Research and Continuing Education, Pusa Road, Rajendra Place New Delhi, 110005, India EC No.: ECR/3/BLK/Inst/DL/2013/RR-19 |
| 3 | Dr. Rahil Farid | Charak Hospital and Research Centre, Hardai Road, Dubbaga, Lucknow-226003, Uttar Pradesh. | Institutional Ethics Committee, Charak Hospital and Research Centre, Hardoi Road, Dubagga, Lucknow-226003, Uttar Pradesh ECR/1255/Inst/UP/2019 |
| 4 | Dr. Chadrashekhar Gillurkar | Gillurkar Multispeciality Hospital, Gillurkar Multispeciality Hospital, 20 reshimbag Umread Road, Nagpur-440009 | Gillurkar Hospital Ethics Committee. EC Address:20, Reshimbag, Umread Road, Nagpur, 440009 ECR/1374/Inst/MH/2020 |
| 5 | Dr. Indra Bhushan Mishra | Heritage Hospitals Ltd., Lanka, Varanasi-221005, Uttar Pradesh | Heritage Hospitals Ethics Committee, Heritage Hospitals Ltd., Lanka, Varanasi-221005 ECR/341/Inst/UP/2013/RR-20 |
| 6 | Dr. Abhishek Patil | KLES Dr. Prabhakar Kore Hospital and MRC, KLES Dr. Prabhkar Kore Hospital and MRC, Nehru Nagar, Belagavi-590010 | Intuitional Ethics Committee, KLE Academy of Higher Education and Research (KAHER), Belagavi, JNMC Campus, Nehru Nagar, Belagavi-590010 ECR/2011/Inst/KA/2013/RR-19 |
| 7 | Dr. Dibyajyoti Karamkar | College of Medicine and Sagore Dutta Hospital, 578, BT Road, Kamarhati, Kolkata-700058 | IEC, College of Medicine & Sagore Dutta Hospital, CMSDH, 578, B.T. Road, Kamarhati, Kolkata-700058 ECR/1210/Inst/WB/2019 |

**Place: New Delhi**

**Date:** .....

16 JUN 2022

**Central Licencing Authority**

**Stamp**

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औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय
एवं परिवार कल्याण मंत्रालय
[illegible], भवन, कोटला रोड़, आई.टी.ओ.
नई दिल्ली-110002