Nil

File No. FDC/MA/21/000146
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:
13 SEP 2021

To,
M/s. Macleods Pharmaceuticals Ltd.,
3rd Floor, Atlanta Arcade, Church Road,
Near Leela Hotel, Andheri-Kurla Road,
Andheri-East, Andheri, Mumbai-400059.

Subject: **Permission to conduct Phase III clinical trial with the FDC of Pioglitazone Hydrochloride IP 15mg + Teneligliptin Hydrobromide Hydrate IP 20mg tablets (Vide protocol no. CT-027-TEPI(F)-2021, Version No. 1.0, dated: 30.06.2021)-regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 30.06.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-143/2021** 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;

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 DRUG

Permission no.: CT-06-143/2021

1. The Central Licencing Authority hereby permits **M/s. Macleods Pharmaceuticals Ltd., 3rd Floor, Atlanta Arcade, Church Road, Near Leela Hotel, Andheri-Kurla Road, Andheri-East, Andheri, Mumbai-400059** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. CT-027-TEPI(F)-2021, Version No. 1.0, dated: 30.06.2021** 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: .....

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: 13 SEP 2021

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Pioglitazone Hydrochloride IP 15mg + Teneligliptin Hydrobromide Hydrate IP 20mg tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Pioglitazone Hydrochloride IP 15mg + Teneligliptin Hydrobromide Hydrate IP 20mg tablets
Indications:	For the treatment of patients with type 2 diabetes mellitus who are inadequately controlled on Metformin Monotherapy.

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-06-143/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Chaware Vinod Subhashrao	Oriion Citicare Super Spreciality Hospital, 5-5-70, Opp. Kalash Mangal Karyalay, New Osmanpura, Auragabad-431005	Oriion Citicare Super Spreciality Hospital, 5-5-70, Opp. Kalash Mangal Karyalay, New Osmanpura, Auragabad-431005 & ECR/1548/Inst/MH/2021
2	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
3	Dr. Manjunath Goroshi	KLES Dr. Prabhakar Kore Hospital and MRC, Nehru Nagar, Belgavi-590010	Institutional Ethics Committee KLE University, Dr. PK Hospital and MRC, Nehru Nagar, Belgavi-590010 & ECR/211/Inst/KA/2013/RR-19
4	Dr. Sanjeev R Phatak	Vijayratna Diabetes Diagnosis & Treatment Centre, Upper ground floor, Sumeru, near Parimal Under bridge & Suvidha Shopping Center, Paldi, Ahmedabad-380007	Thakershy Charitable Trust Ethics Committee, Sushri Jasumatiben Shantilal Surti Charitable General Hospital, Opp. Vimanagar, near Shivrajni Cross Road, Satellite, Ahmedabad-380015 & ECR/696/Inst/GJ/2014/RR-21

Place: New Delhi

Date: .....

12 SEP 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.
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