

Nil

File No. FDC/MA/21/000126
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:

To,

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

11 4 SEP 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin 10mg + Teneligliptin Hydrobromide Hydrate IP 20mg tablets (Vide protocol no. CT-026-DATE(F)-2021, Version No. 1.0, dated: 18.05.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 31.05.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-151/2021** 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-06-151/2021

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-026-DATE(F)-2021, Version No. 1.0, dated: 18.05.2021**) 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: **14 SEP 2021**

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Dapagliflozin 10mg + Teneligliptin Hydrobromide Hydrate IP 20mg tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Dapagliflozin 10mg + Teneligliptin Hydrobromide Hydrate IP 20mg tablets
Indications:	For the treatment of patients with type 2 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


Central Licencing Authority
Stamp

Drugs Controller General of India
Director General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, L.T.O.
New Delhi-110002

Annexure-APermission no.: **CT-06-151/2021**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Vinayak Sawardekar	Grant Government Medical College & Sir JJ Group of Hospitals, JJ Marg, Byculla, Mumbai, Maharashtra-400008.	Institutional Ethics Committee, GGMC, Mumbai ECR/382/Inst /MH/2013/R R-19
2	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
3	Dr. Sudhir Kumar Bhatnagar	Abhinav Multispeciality Hospital Pvt. Ltd. Nagpur, Maharashtra.	Jasleen Hospital Ethics Committee
4	Dr. Prakash Shende	Dr. Shende Cardio Diabetic Clinic & Hospital, Pune, Maharashtra.	IEC-Sai Sneh Hospital and Daignostic Centre
5	Dr. Vinod Chaware	Oriion Citicare Super Specially Hospital, 5-5-70, Opp. Kalash Mangal Karyalay, New Osmanpura, Auragabad-431005	Oriion Citicare Super Specially Hospital, 5-5-70, Opp. Kalash Mangal Karyalay, New Osmanpura, Auragabad-431005 & ECR/1548/Inst/MH/2021
6	Dr. Kamal Sharma	Sanjivani Super Specialty Hospital, Ahmedabad, Gujarat.	Ethics Committee of Ishwar Institute of HealthCare
7	Dr. Pratibha Pereirar.	JSS Hospital, Mysuru, Karnataka	Institutional Ethics Committee JSS Hospital
8	Dr. Balamurgan Ramanathan	Kovai Diabetes Speciality Centre & Hospital Ramnagar,/Coimbatore	Institutional Ethics Committee Kovai Diabetes Speciality Centre and Hospital
9	Dr. Zenith Sinojiya	Sterling Hospital, Rajkot/Gujarat	Sterling Institutional Ethics Committee

Place: New Delhi

Date:

14 SEP 2021V-h
Central Licencing Authority

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Dr. V. G. Soman
Drugs Controller General (India)
Dir. General of Health Services
Ministry of Health and Family Welfare
Government of India, New Delhi