

Nil

File No.FDC/MA/22/000158 ✓

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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. Glenmark Pharmaceuticals Ltd.
Glenmark House, of B2 Mahalaxmi Chambers 22,
Bhula Bhai Desai Road Mumbai, (India)-400026.

04 JUL 2022

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (5mg + 50mg + 500mg & 5mg + 50mg + 1000mg) film coated tablets (Vide protocol no. GPL/CT/2022/003/III, version no. 1.0, dated 12.05.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 13.05.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-53/2022** 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;

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-06-53/2022

1. The Central Licencing Authority hereby permits **M/s. Glenmark Pharmaceuticals Ltd. Glenmark House, of B2 Mahalaxmi Chambers 22, Bhula Bhai Desai Road Mumbai, (India)- 400026, Telephone No.: 2240189999 Fax: 2240189988 E-Mail KishanSingh.Kaira@glenmarkpharma.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. GPL/CT/2022/003/III, version no. 1.0, dated 12.05.2022**) 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:

04 JUL 2022

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (5mg + 50mg + 500mg & 5mg + 50mg + 1000mg) film coated tablets
Therapeutic class:	Anti-diabetic Drug
Dosage form:	Tablets
Composition:	Each film coated tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin + Sitagliptin Phosphate monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (5mg + 50mg + 500mg & 5mg + 50mg + 1000mg)
Indications:	In 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
Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kolla Road, I.T.O.
New Delhi-110002

Annexure-APermission no.: **FDC-CT-06-53/2022**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Saurabh Agarwal	GSVM Medical College, Swaroop Nagar, Uttar Pradesh, Kanpur Nagar, Kanpur-208002	Ethics Committee GSVM Medical College, Room No. 125, First Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002 ECR/680/Inst/UP/2014/RR-20
2	Dr Sanjay Saran	SMS Medical College and attached Hospital, Dept of Endocrinology, room No 43, A forth floor, Dhanvantri OPD Block, Jaipur-302004, Rajasthan	Office of Ethics Committee SMS Medical College and attached Hospital, 2nd floor Academic Block, Jaipur-302004, Rajasthan ECR/26/Inst/RJ/2013/RR-19
3	Dr. R Balamurugan	Kovai Diabetes Speciality Centre & Hospital, 15, Vivekanand Road, Ramnagar, Coimbatore -641009, Tamilnadu.	Institutional Ethics Committee of Kovai Diabetes Speciality Centre & Hospital, 15, Vivekanand Road, Ramnagar, Coimbatore -641009, Tamilnadu. ECR/233/Inst/TN/2013/RR-19
4	Dr. Amol Dange	Lifepoint Multispeciality Hospital, 145/1 Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra	LPR Ethics Committee, Lifepoint Multispeciality Hospital, 145/1 Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra ECR/751/Inst/MH/2015/RR-21

Place: New Delhi

Date:

04 JUL 2022

Central Licencing Authority

Stamp

Dr. V. S. (India)
Drugs Control Services
Dte. General Services
Ministry of Health & Family Welfare
FDA Bhawan, New Delhi, I.T.O.
New Delhi-110002