

Nil

File No. FDC/MA/21/000259
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:

13 DEC 2021

To,

M/s. Sun Pharma Laboratories Ltd.,
Sun House, Plot No. 201 B/1,
Western Express Highway,
Goregaon (E), Mumbai-400063.

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin propanediol monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (5mg + 1mg + 500mg, 5mg + 2mg + 500mg, 5mg + 1mg + 1000mg & 5mg + 2mg + 1000mg) tablets (Vide protocol no. ICR/21/015, version no. 1.0, dated: 14.10.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 03.11.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-201/2021** 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-06-201/2021**

1. The Central Licencing Authority hereby permits **M/s. Sun Pharma Laboratories Ltd., Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai-400063** (Name and full address with contact details of the applicant) to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. ICR/21/015, version no. 1.0, dated: 14.10.2021** 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:

13 DEC 2021

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Dapagliflozin propanediol monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (5mg + 1mg + 500mg, 5mg + 2mg + 500mg, 5mg + 1mg + 1000mg & 5mg + 2mg + 1000mg) tablets
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition:	Dapagliflozin propanediol monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (5mg + 1mg + 500mg, 5mg + 2mg + 500mg, 5mg + 1mg + 1000mg & 5mg + 2mg + 1000mg) tablets
Indications:	Indicated as an adjunct to diet and exercise to improve glycemic control in adults 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, Kotla Road, I.T.O.
New Delhi-110002

Permission no.: CT-06-201/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Gofne Sandip Krishnrao	District Civil Hospital, Near Airport, Jalna Road, Aurangabad- 431007, Maharashtra, India.	Ethics Committee Ajanta Superspeciality Hospital ECR/1499/Inst/MH/2021
2	Dr. Lomte Nilesh Keshavrao	Hormone Care, Room No. 02, 2nd Floor, Oberoi Chambers, Besides Hotel Amarpreet, Jalna Road, Aurangabad-431005	Ethics Committee Ajanta Superspeciality Hospital ECR/1499/Inst/MH/2021
3	Dr. Ravikumar Sethuraman	Levin Diabetes Centre, 555, 14th street, Karpaga Nagar, K. Pudur, Madurai, TN 625007	Saravana Multispeciality Hospital-IEC ECR/1187/Inst/TN/2019
4	Dr. S Vasant Kumar	Gandhi Hospital, Inpatient Block, 3rd Floor, Dept. of general medicine, Musheerabad, Secunderabad, Telangana 500003	Institutional Ethics Committee Gandhi Hospital ECR/180/Inst /AP/2013/RR -19
5	Dr. Gupta Hemant Ramsharan	Grant Govt. Medical College and Sir J J Group of Hospital, OPD No. 20, Department of Internal Medicine, Old OPD Building, Byculla, Mumbai – 400008. Maharashtra	Institutional Ethics Committee, GGMC, Mumbai ECR/382/Inst/ MH/2013/RR19
6	Dr. Shendkar Kaustubh Vijay	Global Hospital and Research Institute, Ground floor, OPD No. 9, Department of Diabetology, 577/2, off Sinhgad Road, near Dattawadi, Pune, Maharashtra 411030	Institutional Ethics Committee of MAEER's Vishwaraj Hospital ECR/1138/Inst /MH/2018
7	Dr. G. Balachandra	BGS Global Institute of Medical Sciences, Ground Floor ,Room No-003, Department of General Medicine, #67,BGS Health and Education City, Uttarahalli Road, Kengeri, Bengaluru560060	Institutional Ethics Committee ECR/1307/Inst /KA/2019
8	Dr. Chikkalingaiah Siddegowda	Medstar Speciality Hospital, #641/17/1/3, Kodigehalli Main Road, Sahakarnagar,Bangalore-560092,Karnataka, India.	Medstar Speciality Hospital Ethics Committee ECR/1324/Inst/KA/2019

9	Dr. Dinesh Jain	Dayanand Medical College & Hospital Research and development Centre, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines Ludhiana, Punjab-141001	Drug Trial Ethics committee Dayanand Medical College & Hospital, Tagore nagar Ludhiana 141001 ECR/101/Inst/ PB/2013/RR19
10	Dr. Surendra Kumar	S. P. Medical College & A.G of Hospitals Bikaner PBM Hospital, Research room, near medicine ICU, Department of medicine, Bikaner, Rajasthan 334001	ETHICS COMMITTEE, S.P.MEDICAL COLLEGE, BIKANER S.P.Medical College, Bikaner Pawanpuri, Bikaner Rajasthan - 334003 India ECR/27/SP/Inst /RJ/2013/RR-19
11	Dr. Surender Kumar	Sir Ganga Ram Hospital, Department of endocrinology and metabolism, SGRH Marg, Rajinder Nagar new delhi 110060	Ethics Committee, Sir Ganga Ram Hospital Old Rajinder Nagar New Delhi New Delhi Delhi – 110060 ECR/20/Inst/DL /2013/RR-19
12	Dr. Sujata Devi	All India Institute of Medical Sciences, AIIMS Bhubaneswar, Department of General Medicine, Sijua P/O Dumduma Orissa-751019	Institutional Ethics Committee, AIIMS Bhubaneswar. ECR/534/Inst /OD/2014/R R-20

Place: New Delhi

Date:

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Central Licencing Authority

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Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health and Family Welfare
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