

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. Alkem Health Science,
A Unit of Alkem Laboratories Ltd., Unit-2,
Samardung, Karek Block, PO: Namthang,
South Sikkim-737137.

06 JUL 2022

Subject: Permission to conduct Phase III clinical trial with the FDC of Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Linagliptin 5mg film coated tablet (Vide protocol no. ALK27-DAL1, version no. 1.0, dated 11.05.2022)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 03.06.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-55/2022** 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-06-55/2022**

1. The Central Licencing Authority hereby permits **M/s. Alkem Health Science, A Unit of Alkem Laboratories Ltd., Unit-2, Samardung, Karek Block, PO: Namthang, South Sikkim-737137, Telephone No.: +918016097300, FAX: +918016097300, Email: katkar@alkem.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. ALK27-DAL1, version no. 1.0, dated 11.05.2022**) 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:

06 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 10mg + Linagliptin 5mg film coated tablet
Therapeutic class:	Antidiabetic
Dosage form:	Tablets
Composition;	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Linagliptin 5mg film coated tablet
Indications:	In patients with Type 2 Diabetes Mellitus inadequately controlled on Metformin

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. C. SOMANI
Drugs Controller General (India)
Dte. G. S. Services
Ministry of Health & Family Welfare
F.D.A. I.T.O.

Permission no.: FDC-CT-06-55/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Girish Bhatia	Medipoint Hospital, 241, 1, New DP Rd, Shambhu Vihar Society, Aundh, Pune, Maharashtra 411007	Penta-Med Ethics Committee Medipoint Hospitals Pvt. Ltd., Medipoint Hospitals Pvt. Ltd. 241/1, New D.P. Road, Near Sai Heritage, Aundh, Pune Maharashtra – 411007, India ECR/357/Inst/MH/20 13/RR-20
2	Dr. Amol Dange	Lifepoint Multispecialty Hospital, No. 145, Sr, 1, Mumbai Pune Bypass Rd, near Sayaji Hotel, Wakad, Pune, Maharashtra 411057	Lifepoint Research Ethics Committee, Lifepoint Multispecialty Hospital Pvt. Ltd., 145/1, MumbaiBangalore highway, Near Hotel Sayaji, Wakad, Pune411057, Maharashtra, India ECR/751/Inst/MH/20 15/RR-21
3	Dr. Sanket Sorate	Sanjeevani Criticare & Research Centre Pvt. Ltd., Narayan Sankul, Dindori road, near Mahalaxmi Talkies, Panchavati, Nashik, Maharashtra 422003	Shree Siddhivinayak Hospital Ethics Committee, Shree Siddhivinayak Maternity And Nursing Home, Unity Campus, 2nd Floor, Opposite KTHM College Gangapur Road, Nashik Maharashtra – 422002, India ECR/1247/Inst/MH/2 019
4	Dr. Onkar Gavli	Lokmanya Multispecialty and Accident Hospital, Dhatri Phata, MumbaiAgra Highway, Near Bali Mandir, Panchavati, Nashik-422003	Shree Siddhivinayak Maternity And Nursing Home Unity Campus, 2nd Floor, Opposite KTHM College Gangapur Road NASHIK Nashik Maharashtra - 422002 India ECR/1247/Inst/MH/2 019
5	Dr. Vaibhav Kothari	Shushrusha Navneet Memorial Hospital, Near Sardar Patel Samaj Sevahall, Opp Navrangpura Telephone Exchange, Ahmedabad, Gujarat - 380009	Sangini Hospital Ethics Committee, Sangini Hospital Santorini Square, B/H Abhishree Complex Opp. Star Bazar, Near Jodhpur Cross Roads Satellite Ahmedabad, Ahmedabad Gujarat – 380015, India ECR/147/Inst/GJ/201 3/RR-19
6	Dr. Arindam Naskar	School of Tropical Medicine, 108, Chittaranjan Avenue, Kolkata, West Bengal 700073	Clinical Research Ethics Committee, School of Tropical Medicine 108 C R Avenue Kolkata 700073- West Bengal, India ECR/194/Inst/WB/20 13/RR-20
7	Dr. Asish Mondal	88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal 700073	Institutional Ethics committee for Human Research, Medical College and hospital, 88 College street, Kolkata -700073, India ECR/287Inst/WB/20 13/RR-19
8	Dr. Harshal Chaudhari	HBT Trauma Care Center, Ajgaokar plot, Western express highway, Jogeshwari (East), Mumbai 400060, Maharashtra, India	Ethics committee of Trauma Care Hospital, Ajgaokar plot, Western Express Highway Jogeshwari East Mumbai, Maharashtra - 400060 ECR/1623/Inst/MH/2 021
9	Dr. S. Suresh Kumar	Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai-600123	Institutional Human Ethics Committee, Panimalar Medical College & Research Institute, Varadharajapuram, Poonamallee, Chennai- 600123 ECR/1399/Inst/TN/2 020

10	Dr. Durga Prasad	Help Hospitals Pvt. Ltd., D. No. 27-29-23, Behind Victoria Museum, M.G. Road, Governorpet, Vijaywada- 520 002, Andhra Pradesh, India	Help Hospitals Pvt. Ltd., D. No. 27-29-23, Behind Victoria Museum, M.G. Road, Governorpet, Vijaywada- 520 002, Andhra Pradesh ECR/1356/Inst/ AP/ 2020
11	Dr. Laxmikant Goyal	Sawai Man Singh Medical College and Hospital, Gangawal Park, Adarsh Nagar, Jaipur, Rajasthan 302004	Ethics Committee S.M.S. Medical College and Attached Hospitals, J.L.N. Marg, Rajasthan - 302004 ECR/26/Inst/RJ/2013 /RR-19
12	Dr. Mahesh Babu	Meenakshi Mission Hospital & Research Centre, Lake Area, Melur Main Rd, Madurai, Tamil Nadu 625107	Institutional Ethics Committee, Meenakshi Mission Hospital and Research Centre, Lake Area, Melur Road, Madurai, Tamil Nadu 625107 ECR/398/Inst/TN/20 13/RR-19
13	Dr. Vipul Khandelwal	Apex Hospital Pvt. Ltd., S P 4 & 6 Malviya Industrial Area, Malviya Nagar, Jaipur - 302017, Rajasthan	Institutional Ethics Committee Apex Hospitals Private Limited SP 4 and 6 Industrial Area, Malviya Nagar Jaipur Rajasthan - 302017 India ECR/380/Inst/RJ/201 3/RR-19
14	Dr. Rakesh Kumar Sahay	Osmania General Hospital, 15-5-104, Begum Bazar, Afzal Gunj, Hyderabad, Telangana 500012	Osmania Medical College, koti, Hyderabad, 500095 Hyderabad Telangana - 500095 India ECR/300/Inst/AP/20 13/RR-19
15	Dr. Harish Kumar	Amrita Institute of Medical Sciences & Research Centre, Ponekkara, Kochi, Kerala, 682041	Institutional Ethics Committee Amrita Institute of Medical Sciences AIMS Ponekkara Kochi Edappally Ernakulam Kerala - 682041 India ECR/129/Inst/KL/20 13/RR-19
16	Dr. Dhaiwat Shukla	V.S. General Hospital. Ellisbridge, Ahmedabad, Gujarat- 380006	Shrey Hospital Institutional Ethics Committee Shrey Hospital Private Limited 270/B/5 Near AMCO Bank, Stadium Circle Navrangpura Ahmedabad Gujarat - 380009 India ECR/1302/Inst/GJ/20 19

Place: New Delhi

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Central Licencing Authority

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