

Nil

File No. FDC/MA/22/000061

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Govt. of India

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Directorate General of Health Services  
Central Drug Standard Control Organization  
(FDC Division)

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated:

To,

M/s. Micro Labs Ltd.,  
Mamring, Namthang Road,  
South Sikkim-737132, Karnataka

31 MAY 2022

**Subject:** Permission to conduct Phase III clinical trial with the FDC of Linagliptin 5mg + Dapagliflozin 10mg tablets (Vide protocol no. MLDPN/11/2021 version no. 1.0, dated: 10.11.2021)-regarding.

Dear Sir,

With reference to your online application submitted in CT-21 on dated 25.02.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. FDC-CT-06-46/2022 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;
- 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 Licencing 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;

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR  
INVESTIGATIONAL NEW DRUG**

Permission no.: FDC-CT-06-46/2022

1. The Central Licencing Authority hereby permits **M/s. Micro Labs Ltd., Mamring, Namthang Road, South Sikkim-737132, Karnataka, Telephone no. 917063589735, Fax: 917063589735** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**Vide protocol no. MLDPN/11/2021 version no. 1.0, dated: 10.11.2021**) 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: .....

**31 MAY 2022**

✓  
Central Licencing Authority

Stamp

डॉ. वी. जी. सोमानी  
औषधि महानियंत्रक (भारत)  
स्वास्थ्य सेवा महानिदेशालय  
स्वास्थ्य एवं परिवार कल्याण विभाग  
एन.डी.ओ. भवन, फोर्टस रोड, आई.टी.ओ.  
नई दिल्ली-110002

Annexure:

Details of new drug or investigational new drug:

<b>Names of the new drug or investigational new drug:</b>	Linagliptin 5mg + Dapagliflozin 10mg tablets
<b>Therapeutic class:</b>	Antidiabetic
<b>Dosage form:</b>	Tablets
<b>Composition:</b>	Each tablets contains: Linagliptin ..... 5mg Dapagliflozin ..... 10mg
<b>Indications:</b>	In patients with Type 2 Diabetes Mellitus

Details of clinical trial site:

<b>Names and address of clinical trial site:</b>	As per annexure- A
<b>Ethics committee details:</b>	As per annexure- A
<b>Name of principal investigator:</b>	As per annexure- A



Permission no.: FDC-CT-06-46/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Parminder Singh	Dayanand Medical College Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001, Punjab	Ethics Committee Office, Basement Hero DMC Heart Institute Dayanad Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001, Punjab ECR/101/Inst/PB/2013/RR-19
2	Dr. Ved Prakash	Dept. of Endocrinology, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar-800014	Instituional Ethics Committee, Indira Gandhi Institute of Medical Sciences, Sheikhpura, Patna, Bihar-800014 ECR/640/Inst/BR/2014/RR-20
3	Dr. S K Sharma	Diabetes Thyroid & Endocrine Center, A-1, Madrampura, Near 4 No. ESI Hospital, Ajmer Road, Sodala, Jaipur-302006, Rajasthan	Human Welfare Ethical Committee for Human Sciences and Research, Diabetes, Thyroid & Endocrine Center A-1, Madrampura, Near 4 No. ESI Hospital, Ajmer Road, Sodala, Jaipur-302006, Rajasthan ECR/36/Inst/RJ/2013/RR-19
4	Dr Mala Dharmalingam	Bangalore Endocrinology and Diabetes Research Center, BEDRC, #35, 5 <sup>th</sup> Cross, Bangalore-560003	Ethics Committee, Shetty's Hospital, Plot No. 11 & 12, 12 <sup>th</sup> F Main, Kaveri Nagar, Kodichikkanahalli, Bommanahalli, Bangalroe-560068, Karnataka ECR/918/Inst/KA/2017/RR-20
5	Dr A Shanmugam	Dr Ambedkar Institute of Diabetes Govt Kilpauk Medical College & Hospital, Chennai	Govt Kilpauk Medical College & Hospital, Chennai-10 ECR/1385/Inst/TN/2020
6	Dr. Sreenivasamurthy L.	Lifecare Hospital and Research Centre, #2748/2152, M.I.N. Enclave, 16 <sup>th</sup> E Cross Road, 8 <sup>th</sup> Main, D Block, Next to Corporation Bank, Sahakarnagar, Bangalore-560092	Life Care Hospital Institutional Review Board, #2748/2152, M.I.N. Enclave, 16 <sup>th</sup> E Cross Road, 8 <sup>th</sup> Main, D Block, Next to Corporation Bank, Sahakarnagar, Bangalore-560092 ECR/883/Inst/KA/2017/RR-20
7	Dr. Balamurugan Ramanathan	Kovai Diabetes Speciality Centre and Hospital, No. 15, Vivekananda Road, Ram Nagar, Coimbatore-641009	Kovai Diabetes Speciality Centre and Hospital, No. 15, Vivekananda Road, Ram Nagar, Coimbatore-641009 ECR/233/Inst/TN/2013/RR-19
8	Dr. A. Gopal Rao	Government Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh	Institutional Ethics Committee Govt. Medical College Govt. General Hospital Balaga, Srikakulam Andhra Pradesh - 532001 ECR/492/Inst/AP/2013/RR-20
9	Dr. Animesh Maiti	Dept. of Endocrinology, Medical College and Hospital, Kolkata 88, College Street, Kolkata-700073, West Bengal	Institutional Ethics Committee for Human Research, Medical College and Hospital, Kolkata 88, College Street, Kolkata-700073, West Bengal ECR/287/Inst/WB/2013/RR-20
10	Dr Mohan Magdum	Jehangir Clinical Development Center Pvt. Ltd., Jehangir Hospital Premises, 32 Sassoon Road, Pune-411001	Ethics Committee Jehangir Clinical Development Centre Pvt. Ltd., Jehangir Hospital Premises, 32 Sassoon Road, Pune-11001 ECR/352/Inst/MH/2013/RR-19

11	Dr. D. V. Ogale	B J Medical College and Sassoon General Hospital, 3 <sup>rd</sup> Floor, Dept. of Medicine, Somwar Peth, Sassoon Road, Pune	Institutional Ethics Committee B J Medical College and Sassoon General Hospital, 3 <sup>rd</sup> Floor, Dept. of Medicine, Somwar Peth, Sassoon Road, Pune ECR/433/Inst/MH/2013/RR-19
12	Dr Prajapati Vipulkumar	GCS Medical College, Hospital & Research Center, Opp. DRM Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad -380025, Gujarat	Institutional Ethics Committee , GCS Medical College, Hospital & Research Center, Opp. DRM Office, Nr. Chamunda Bridge, Naroda Road, Ahmedabad -380025, Gujarat ECR/339/Inst/GJ/2013/RR-19

Place: New Delhi

Date: .....

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*V. J.*

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