

Nil

File No. FDC/MA/21/000134 ✓  
Govt. of India

Tele. No. :011-23236965  
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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 Limited,  
Mamring, Namthang Road,  
South Sikkim-737132.

21 SEP 2021


**Subject:** Permission to conduct Phase III clinical trial with the FDC of Bisoprolol IP 5mg + Telmisartan IP 40mg tablets (Vide protocol no. MLBTL/05/2021, version no. 2.0, dated: 05.08.2021)-regarding.

Dear Sir,

With reference to your online application submitted in CT-21 on dated 07.06.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-156/2021 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;
- 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;

**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-06-156/2021**

1. The Central Licencing Authority hereby permits **M/s. Micro Labs Limited, Mamring, Namthang Road, South Sikkim-737132** (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. MLBTL/05/2021, version no. 2.0, dated: 05.08.2021**) 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: .....**

**21 SEP 2021**

**Annexure:**

**Details of new drug or investigational new drug:**

<b>Names of the new drug or investigational new drug:</b>	Bisoprolol IP 5mg + Telmisartan IP 40mg tablets
<b>Therapeutic class:</b>	Antihypertensive
<b>Dosage form:</b>	Tablets
<b>Composition:</b>	Bisoprolol IP 5mg + Telmisartan IP 40mg tablets
<b>Indications:</b>	In the treatment of Stage 1 and Stage 2 Hypertension

**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

*V. G. S.*  
**Central Licencing Authority**

Dr. V. G. S. **Stamp**  
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-06-156/2021

S.No	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr C N Manjunath Professor of Cardiology and Director	Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bangalore, Karnataka- 560069	ECR/423/Inst/KA/2013/RR-19
2	Dr Padmanabh Kamath Prof. and HOD, Department of Cardiology	KMC Hospital, Mangalore, Karnataka575001	ECR/541/Inst/KA/2014/RR-20
3	Dr Gurpreet S. Wander Professor, Dept of Cardiology	Dayanand Medical College & Hospital , Ludhiana, Punjab - 141001	ECR/101/Inst/PB/2013/RR-19
4	Dr Bhim Ram Assistant Professor Dept of General Medicine	Indira Gandhi Institute of Medical sciences. Sheikhpura, Patna, Bihar - 800 014	ECR/640/Inst/BR/2014/RR-20
5	Dr. Satyendra Kumar Sonkar Professor, Dept. of Medicine	King Georges Medical University Lucknow, Uttar Pradesh - 226003	ECR/262/Inst/UP/2013/RR-19
6	Dr Debabrata Roy Senior Consulting Interventional Cardiologist & Academic Co- ordinator	Rabindranath Tagore International Institute of Cardiac Sciences, Kolkata, West Bengal - 700 099	ECR/316/Inst/WB/2013/RR-19
7	Dr S.S.V.V. Narasinga Rao Assistant Professor, Dept of General Medicine	Rajiv Gandhi Institute of Medical Sciences & Govt. General Hospital, Srikakulam, Andhra Pradesh-532001	ECR/492/Inst/AP/2013/RR-20
8	Dr Prajapati Vipulkumar Bachubhai Associate Professor Dept of General Medicine	GCS Medical College, Hospital & Research Center, Naroda Road, Ahmedabad, Gujarat- 380025	ECR/339/Inst/GJ/2013/RR-19
9	Dr. L. Sreenivasamurthy Prof of medicine, & Medical Director	Lifecare Hospital and Research Centre, Bangalore, Karnataka -560092	ECR/883/Inst/KA/2017/RR-20
10	Dr. R. Balamurugan Senior Consultant and Head	Kovai Diabetes Speciality Centre and Hospital Vivekananda Road Coimbatore Tamil Nadu - 641009	ECR/233/Inst/TN/2013/RR-19

Place: New Delhi

Date: .....

21 SEP 2021

Vhr  
Central Licencing Authority  
Stamp

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