NIL

File No.FDC/MA/23/000176
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: 27 DEC 2023

To,

M/s. Akums Drugs and Pharmaceutical Ltd.,
Plot No. 19,20,21, Sector 6A, I.I.E., SIDCUL,
Ranipur, Haridwar, Uttarakhand 249403.

Subject: Permission to conduct Phase III clinical trial with the FDC of Cilnidipine IP 10mg + Bisoprolol Fumarate IP 5mg film coated tablet (Vide protocol no. BRPL/CT/FDC/BCILN/05/23, version no. 2.0, dated 07.11.2023)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 20.06.2023 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-70/2023** 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. Rajeev Singh Raghuvanshi)
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; 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;

IV. 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.: FDC-CT-06-70/2023

1. The Central Licencing Authority hereby permits **M/s. Akums Drugs and Pharmaceutical Limited, Plot No. 19,20,21, Sector 6A, I.I.E., SIDCUL, Ranipur, Haridwar, Uttarakhand 249403, Telephone No: 1334239220, Fax: 1334239220** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(BRPL/CT/FDC/BCILN/05/23, version no. 2.0, dated 07.11.2023)** 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: .....

7 DEC 2023

Annexure:

Central Licencing Authority

Dr. RAJEEV SINGH RAGHUVANSHI
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi-110002

Stamp

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Cilnidipine IP 10mg + Bisoprolol Fumarate IP 5mg film coated tablets
Therapeutic class:	Antihypertensive
Dosage form:	Film coated tablet
Composition:	Each film coated tablets contains: Cilnidipine IP .... 10mg Bisoprolol Fumarate IP 5mg
Indications:	It is indicated for the treatment of essential hypertension associated with coronary artery disease (CAD)

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

Annexure-A

Permission no.: FDC-CT-06-70/2023

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1.	Dr. T. Krishna Kumar	Excel Hospital, 1-5-56/29, Plot No : 29, Old Alwal, Near IG Statue beside Bharat Petroleum, Secunderabad, Telangana - 500010	Excel Hospital Institutional Ethics Committee, A Unit of Bhargava Sai Healthcare, 1-5-56/29, Plot No : 29, Old Alwal, Near IG Statue beside Bharat Petroleum, Secunderabad, Telangana - 500010 ECR/1670/Inst/TG/2022
2.	Dr. Amaresh kumar Singh	Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomtinagar, Lucknow, Uttar Pradesh 226010	Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute of Medical Sciences Research Cell Office Room No. 35 2nd Floor Administrative Block, RMLIMS Lucknow,Lucknow Uttar Pradesh 226010India ECR/913/Inst/UP/2017/RR-20
3.	Dr. Bhosale Karthik Hanumant	Medipoint Hospitals Private Limited, 241/1 New D.P Road, Aundh, Pune411007, Maharashtra	Pentamed Ethics Committee, Medipoint Hospitals Private Limited, 241/1 New D.P Road, Aundh, Pune411007, Maharashtra ECR/357/Inst/MH/2013/RR-20
4.	Dr. Gouranga Sarkar	IPGME&R SSKM Hospital, 244, A.J.C. Bose Road, Kolkata 700020,West Bengal, India	IPGME&R Research Oversight Committee , 244, A.J.C. Bose Road, Kolkata 700020, West Bengal, India EC Reg: ECR/35/Inst/WB/2013/RR-19

Place: New Delhi

Date: .....

27 DEC 2023

Central Licencing Authority

Stamp

Dr. RAJEEV SINGH RAGHUVANSHI
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi (India)