

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

FDA Bhawan, Kotla Road
New Delhi-110002

Dated:

To,

M/s. Inventia Healthcare Pvt. Ltd.,
F1-F1/1, Additional Ambernath M.I.D.C.,
Ambernath-421506.

30 JUL 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Azilsartan Medoxomil 80mg + Amlodipine 5mg tablets (Vide protocol no. CR/CT/18/001, version no. 00, dated: 23.07.2018)-regarding.

Dear Sir,

With reference to your online application submitted in Form 44 on dated 07.01.2019 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-109/2021** 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-06-109/2021**

1. The Central Licencing Authority hereby permits **M/s. Inventia Healthcare Pvt. Ltd., F1-F1/1, Additional Ambernath M.I.D.C., Ambernath-421506.** (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. CR/CT/18/001, version no. 00, dated: 23.07.2018)** 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:

Annexure: **30 JUL 2021**

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Azilsartan Medoxomil 80mg + Amlodipine 5mg tablets
Therapeutic class:	Antihypertensive
Dosage form:	Tablets
Composition:	Azilsartan Medoxomil 80mg + Amlodipine 5mg tablets
Indications:	For the treatment of stage 2 hypertension

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

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Srabani Ghosh	Dept of Medicine, 4th Floor, Ronald Ross Building, IPGME&R and SSKM Hospital, 244, AJC Bose Road, Kolkata-700020.	Ethics Committee, IPGME&R Research Oversight Committee Institute of Postgraduate Medical Education & Research, Office of the Dean, College Building, 5th Floor 244 Acharya J.C. Bose Road Kolkata-700020, India ECR/35/Inst/WB/2013/ RR-16
2	Dr. Girish Veeranna Hiregoudar	Apple Saraswati Multispecialty Hospital, 804/2, 805/2, Circuit House to Kadamwadi Road, Bhosalewadi, Kolhapur-416003, Maharashtra.	Institutional Ethics Committee, Apple Saraswati Multispecialty Hospital, Bhosalewadi, Kolhapur-416001, Maharashtra. ECR/785/Inst/MH/2015
3	Dr. Sagar Vivek Redkar	Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oshalbag, Village-Dhargal, Tal-Pernem, Goa-403 513.	Redkar Hospital Institutional Ethics Committee (RHIEC), Redkar Hospital and Research Centre, Mumbai-Goa Highway, Oxelbag, Dhargal, Pernem, Goa-403513. ECR/902/Inst/GA/2018
4	Dr. Vinayak Ekanath Shegokar	Chandulal Chandrakar Memorial Medical College & Hospital, Kanchandur, Kurud Road, Durg, Chhattisgarh-490024.	Institutional Ethics Committee, Chandulal Chandrakar Memorial Medical College, Kanchandur, Kurud Road, Durg, Chhattisgarh-490024. ECR/790/Inst/CG/2015
5	Dr. K. Sunil Naik	Department of Medicine, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001, Andhra Pradesh, India.	Institutional Ethics Committee, Rajiv Gandhi Institute of Medical Sciences & RIMS Government General Hospital, Srikakulam-532001, Andhra Pradesh, India ECR/492/Inst/AP/2013/ RR-16
6	Dr. D. Anil Kumar	Department of General Medicine, Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana.	Institutional Ethics Committee, Gandhi Medical College/Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana, India. ECR/180/Inst/AP/2013/ RR-16
7	Dr. Barama Srihari	Dept. of Cardiology, Osmania Medical College & General Hospital, Afzalgunj, Hyderabad, Telangana-500012, India.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500095, Telangana State, India. ECR/300/Inst/AP/2013/RR-16
8	Dr. Mukund Anant Deshpande	Department of Cardiology, Government Medical College and Super Specialty Hospital, Tukdoji Square, Near Hanuman Nagar, Nagpur-440009, Maharashtra, India.	Institutional Ethics Committee, Government Medical College, Nagpur, India. ECR/43/Inst/MH/2013/RR-16
9	Dr. Surender Deora	All India Institute of Medical Sciences, Basni Industrial Area, Phase-2, Jodhpur, Rajasthan-342005.	Institutional Human Ethics Committee, All India Institute of Medical Sciences, Basni, Jodhpur-342005, Rajasthan, India. ECR/866/Inst/RJ/2016

10	Dr. Richa Giri	Department of Medicine, Dr. Ram Manohar Lohia Combined Hospital, Vibhuti Khand, Gomati Nagar, Lucknow-226010, Uttar Pradesh.	Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute Medical Sciences, Research Cell Office, Room No. 35, 2nd Floor, Administrative Block, RMLIMS, Lucknow-226010, Uttar Pradesh, India. ECR/913/Inst/UP/2017
11	Dr. Ajay Bansal	Bansal Hospital and Research Centre, 04, Janakpuri-Ist, Imli Phatak, Jaipur-302005, Rajasthan.	Institutional Ethics Committee, Bansal Hospital & Research Centre, 04, Janakpuri First, Imli Phatak, Jaipur-302005, Rajasthan. ECR/826/Inst/RJ/2016
12	Dr. Amit Bhaskar	Janta Hospital, Near Water Head Tank, Amara Akhari Bypass, Chunar Road, Varanasi-221011, Uttar Pradesh.	Janta Hospital Ethics Committee, Survey No. 374, Near Water Head Tank, Amara Akhari Bypass, Chunar Road, Varanasi-221011, Uttar Pradesh. ECR/839/Inst/UP/2016

Place: New Delhi

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N.W.
Central Licencing Authority

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