Nil

File No. FDC/MA/22/000097
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:
14 JUN 2022

To,
M/s. Ajanta Pharma Ltd.,
Ajanta House, Charkop, Kandivali (West),
Mumbai-400067.

Subject: **Permission to conduct Phase III clinical trial with the FDC of Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) + Amlodipine Besilate IP eq. to Amlodipine + Chlorthalidone IP (50mg + 5mg + 6.25mg & 50mg + 5mg + 12.5mg) film coated bilayered tablets (Vide protocol no. APL/CT/22/04, version no. 00, dated: 03.03.2022)-regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 31.03.2022 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-50/2022** 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 Licensing Authority prior to seeking approval of another Ethics Committee for the protocol for conduct of the clinical trial at the same 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-06-50/2022

1. The Central Licencing Authority hereby permits **M/s. Ajanta Pharma Ltd., Ajanta House, Charkop, Kandivali (West), Mumbai-400067, Tel no. 02269132111, Email: shailesh.singh@ajantapharma.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. APL/CT/22/04, version no. 00, dated: 03.03.2022)** 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: .....

14 JUN 2022

Central Licencing Authority

Stamp

डॉ. वी. जी. सोमानी
औषधि महानियंत्रक (भारत)
स्वास्थ्य सेवा महानिदेशालय

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) + Amlodipine Besilate IP eq. to Amlodipine + Chlorthalidone IP (50mg + 5mg + 6.25mg & 50mg + 5mg + 12.5mg) film coated bilayered tablets
Therapeutic class:	Antihypertensive
Dosage form:	Tablets
Composition:	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) + Amlodipine Besilate IP eq. to Amlodipine + Chlorthalidone IP (50mg + 5mg + 6.25mg & 50mg + 5mg + 12.5mg)
Indications:	For patients with uncontrolled essential 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

Annexure-A

Permission no.: FDC-CT-06-50/2022

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1	Dr. Mahmodullah Razi	LPS Institute of Cardiology, GSVM Medical College, Kanpur-208002, Uttar Pradesh, India.	Ethics Committee, G.S.V.M. Medical College, Principal Office, G.S.V.M Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh, India. ECR/680/Inst/UP/2014/RR-20
2	Dr. Raja Bhattacharya	Medical College and Hospital, Kolkata MCH Building 4th, Floor 88 college street, Kolkata -700073, WB, India	Institutional Ethics Committee for Human Research Medical College and hospital, Kolkata MCH Building 4th Floor 88 college street Kolkata 700073, WB ECR/287/Inst/WB/2013/RR-19
3	Dr. Sachin Shivnitwar	Lifepoint Multispecialty Hospital, 145-1 Mumbai-Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra	LPR Ethics Committee Lifepoint Multispecialty Hospital, 145-1 Mumbai-Bangalore Highway, Near Hotel Sayaji, Wakad, Pune 411057, Maharashtra ECR/751/Inst/MH/2015/RR-21
4	Dr. Sandesh Patil	Shree Siddhivinayak Maternity & Nursing Home, Unity Campus, Opposite K.T.H.M. College, Gangapur Road, Nashik 422002, Maharashtra	Shree Siddhivinayak Hospital Ethics Committee Shree Siddhivinayak Maternity & Nursing Home, Unity Campus, Opposite K.T.H.M. College, Gangapur Road, Nashik 422002, Maharashtra ECR/1247/Inst/MH/2019
5	Dr. Vaishal Shah	Lifeline Hospital, Vishal complex, S.V. Road, Opp. N.L. High School, Malad (W), Mumbai-400064	Shah Life line Hospital and Heart Institute Ethics Committee Geeta Nagar, Phase 7 Mira Bhaynader Road, Near Fly Over Bridge, Mira Road (E) Thane-401107 ECR/1588/Inst/MH/2021
6	Dr. Yandrapati Gnanna Sundara Raju	Department of General Medicine, King George Hospital, Maharanipeta, Vishakhapatnam-530002, Andhra Pradesh	Institutional Ethics Committee, King George Hospital, Maharanipeta, Vishakhapatnam-530002, Andhra Pradesh ECR/197/Inst/KGH/2013/RR-20
7	Dr. Ajit Mehta	Jehangir Clinical Development Centre Pvt. Ltd., Jehangir Hospital -411001 Premises, 32-Sassoon Road Pune	Ethics Committee Jehangir Clinical Development Centre Pvt. Ltd. Jahangir Hospital Premises, 32-Sassoon Road Pune-411001 ECR/352/Inst/MH/2013/RR-19
8	Dr. Nikhil Jadhav	Asian Institute of Medical Sciences, P-72, Milap Nagar, MIDC, Dombivli (E) 421203	Suraksha Ethics Committee, Asian Institute of Medical Sciences, P-72, Milap Nagar, MIDC, Dombivli (E)-421203 ECR/ 644/Inst/MH/2014/RR-20

Place: New Delhi

Date: 14 JUN 2022

Central Licencing Authority

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डी. जी. सी. आई.
औषधि महानियंत्रक (भारत)
केन्द्रीय औषध मानक नियंत्रण संगठन