

FDA Bhawan, Kotla Road  
New Delhi-110002

Dated:

To,

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

27 AUG 2021

**Subject:** Permission to conduct Phase III clinical trial with the FDC of Efonidipine Hydrochloride Ethanolate 40mg + Telmisartan IP 40mg film coated bilayered tablet (Vide protocol no. APL/CT/21/03, version no. 00, dated: 18.02.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 15.06.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-134/2021** 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-06-134/2021

1. The Central Licencing Authority hereby permits **M/s. Ajanta Pharma Ltd., Ajanta House, Charkop, Kandivli (West), Mumbai-400067** (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. APL/CT/21/03, version no. 00, dated: 18.02.2021**) 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: 27 AUG 2021

  
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

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Efonidipine Hydrochloride Ethanolate 40mg + Telmisartan IP 40mg film coated bilayered tablet
Therapeutic class:	Efonidipine Hydrochloride Ethanolate: Dihydropyridine (DHP) calcium channel blocker. Telmisartan: Angiotensin II receptor blockers (ARBs)
Dosage form:	Tablets
Composition:	Efonidipine Hydrochloride Ethanolate 40mg + Telmisartan IP 40mg film coated bilayered tablet
Indications:	It is indicated for the management 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

Permission no.: CT-06-134/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Sujata Devi	Department of General Medicine, AIIMS Bhubaneswar Sijua, Patrapada, Bhubaneswar-751019, Odisha	Institutional Ethics Committee, AIIMS Bhubaneswar All India Institute of Medical Sciences, BBSR AIIMS Bhubaneswar Sijua P/O Patrapada Bhubaneswar Khordha Orissa - 751019 India <b>ECR/534/Inst/OD/2014/RR-20</b>
2	Dr. Siddanathi. Narasinga Rao	Department of Medicine, Rajendra Prasad Ward, Clinical Research Room, King George Hospital. Maharani Peta, Visakhapatnam-530002 Andhrapradesh, India.	IEC King George Hospital, King George Hospital, Maharani Peta Collector Office Junction Visakhapatnam Andhra Pradesh - 530002 India <b>ECR/197/Inst/KGH/2013/RR-20</b>
3	Dr. Santosh Saklecha.	Santosh Hospital, 6/1, Promenade Road, Behind Coles Park, Near Goodwill School, Bangalore-560005, Karnataka, India	Santosh Hospital-Institutional Ethics Committee, Santosh Hospital 6/1, Promenade Road Behind Coles Park, Near Goodwill School Bengaluru Karnataka - 560005, India <b>ECR/1062/Inst/KA/2018/RR-21</b>
4	Dr Sunil Kumar Mahavar	Department of Medicine G-1 Dhanvantri OPD Block, SMS Hospital Jaipur-302004, Rajasthan	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur Jaipur Rajasthan - 302004, India <b>ECR/26/Inst/RJ/2013/RR-19</b>
5	Dr. Satish Kumar KN	Department of Medicine Sparsh Super Speciality Hospital, 4/1, Tumkur Road, Yeshwanthpur, Bangalore 560022.	Institutional Ethics committee Sparsh Hospital Sparsh Hospital For Advanced surgeries. No. 146 Opposite Police commissioner Office Infantry Road Bengaluru Karnataka-560001 India <b>ECR/520/Inst/KA/2014/RR-20</b>
6	Dr. Mohan Kumar Singh	W Pratiksha Hospital, Golf Course Extension Road, Sushant Lok II, Sector 56, Gurugram-122011	North East Healthcare Private Limited, Golf Course Ext. Road, Sushantlok II, Sector 56, Gurugram, Haryana 122011, India <b>ECR/1282/Inst/HR/2019</b>
7	Dr. Swapan Kumar Halder	Department of Cardiology, NRS Medical College & Hospital, 138, A.J.C Bose Road, Kolkata-700014, West Bangal, India.	Institutional Ethics Committee, NRS Medical College & Hospital, 138, A.J.C. Bose Road, Kolkata-700014, West Bangal, India. <b>ECR/69Inst/WB/2014/RR-20</b>
8	Dr. Pravin Nagulal Soni	Dept. of General Medicine, PCMC'S PGI Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra, India.	Institutional Ethics Committee, PCMC'S PGI Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, pune-411018, Maharashtra, India. <b>ECR/1236/Inst/MH/2019</b>

Place: New Delhi

Date: 27 AUG 2021
  
**Central Licensing Authority**

 Drugs Controller, General (India)  
 Dte. General of Health Services  
 Ministry of Health and Family Welfare  
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