8751/10.07.19

File No. FDC/MA/19/000029 ✓

Tele. No.:011-23236965
Fax No. :011-23236973

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

FDA Bhawan, Kotla Road
New Delhi-110002
Dated:

03 SEP 2019

To,
M/s. Ajanta Pharma Ltd.,
Plot No. 43 AB & 44 BCD,
Charkop, Kandivali (W),
Mumbai-400067.

Subject: **Permission to conduct clinical trial with the FDC of Efonidipine Hydrochloride Ethanolate + Telmisartan IP + Chlorthalidone IP (20mg + 40mg + 12.5mg & 10mg + 40mg + 12.5mg) tablets (Vide protocol no. APL/CT/18/07, version no. 01, dated: 11.04.2019)-regarding.**

Dear Sir,

With reference to your letter No. APL/DRA/DCGI/19/224 dated 20.05.2019 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-Drugs/73/2019** 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:

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:

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 [illegible]

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;

VI. Clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices Guidelines and the provisions of these rules;

VII. Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

VIII. Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority.

IX. In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

X. Any report of serious adverse event occurring during clinical trial to a subject of clinical trial, shall, after due analysis, be forwarded to the Central Licencing Authority, the chairperson of the Ethics Committee and the institute where the trial has been conducted within fourteen days of its occurrence as per Table 5 of the Third Schedule and in compliance with the procedures as specified in Chapter VI;

XI. In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

XII. In case of clinical trial related death or permanent disability of any subject of such trial during the trial, compensation shall be provided in accordance with Chapter VI and details of compensation provided in such cases shall be intimated to the Central Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority in accordance with the provisions of the said Chapter;

XIII. The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing Authority, to verify compliance of the requirements of these rules and Good Clinical Practices Guidelines, to inspect, search and seize any record, result, document, investigational product, related to clinical trial and furnish reply to query raised by the said officer in relation to clinical trial;

XIV. The laboratory owned by any person or a company or any other legal entity and utilised by that person to whom permission for clinical trial has been granted used for research and development, shall be deemed to be registered with the Central Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing Authority;

XV. The Central Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;

XVI. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

XVII. Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.

XVIII. In addition to the requirement of obtaining written informed consent, an audio-video recording of the informed consent process in case of vulnerable subjects in clinical trial of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record, as per Government of India, Gazette Notification vide G. S. R. no. 611(E) dated 31.07.2015;

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-Drugs/73/2019

1. The Central Licencing Authority hereby permits **M/s. Ajanta Pharma Ltd., Plot No. 43 AB & 44 BCD, Charkop, Kandivali (W), 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 **APL/CT/18/07, version no. 01, dated: 11.04.2019** 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: .....

Date: 03 SEP 2019

Central Licencing Authority

Stamp

Dr. V. G. SOMANI
Drugs Controller General (India)
Directorate 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 + Telmisartan IP + Chlorthalidone IP (20mg + 40mg + 12.5mg & 10mg + 40mg + 12.5mg) tablets
Therapeutic class:	Antihypertensive
Dosage form:	Tablets
Composition:	Efonidipine Hydrochloride Ethanolate + Telmisartan IP + Chlorthalidone IP (20mg + 40mg + 12.5mg & 10mg + 40mg + 12.5mg) tablets
Indications:	For treatment of subjects with uncontrolled essential hypertension; uncontrolled on dual antihypertensive drug therapy

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

INVESTIGATORS NAME

Sr. No.	Investigators Name	Sites Name	Ethics Committee	EC Registration Number
1	Dr. Ajay Bansal	Bansal Hospital & Research Centre, 04, Janakpuri-1°, 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
2	Dr. Basudev Prasad Priyadashi	Post Graduate Department of Medicine, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh.	Ethics Committee, GSVM Medical College, Principal Office, Swaroop Nagar, Kanpur-208002,Uttar Pradesh.	ECR/680/Inst/UP/2014/RR-17
3	Dr. Manish Gutch	Mother and Child State Referral Hospital, Amar Sheed Path, Near Dial 100 Police Office, Gomati Nagar, Lucknow-226002, Uttar Pradesh.	Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute of Medical Sciences, Research Cell Office, Room No. 35, 2" Floor, Administrative Block, RMLIMS, Lucknow-226010, Uttar Pradesh	ECR/913/Inst/UP/2017
4	Dr. Sudhir Kumar Verma	King George's Medical University, Lucknow-226003, Uttar Pradesh.	Institutional Ethics Committee, Office of Research Cell, Administrative Block,King George's Medical University, Lucknow-26003, Uttar Pradesh.	ECR/262/Inst/UP/2013/RR-16
5	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
6	Dr. Anupam Mandal	Dept. of Medicine, 40' Floor, Ronald Ross Building, IPGME&R and SSKM Hospital, 244, AJC Bose road, Kolkata-700020, West Bengal	Ethics Committee, IPGME&R Research Oversight Committee, Institute of Postgraduate Medical Education & Research, Office of the Dean, College Building, 5U Floor, 244, Acharya J.C. Bose road, Kolkata-700020, West Bengal.	ECR/35/Inst/WB/2013/RR-16
7	Dr. Sahid Imam Mallick	NRS Medical College & Hospital, 138, AJC & Hospital, 138, AJC Bose Hospital, 138, AJC Bose Road,	NRS Ethics Committee, NRS Medical College Bose Hospital, 138, AJC Bose Road, Kolkata-700014, West Bengal.	ECR/609/Inst/WB/2014/RR-17