

Nil

File No. FDC/MA/19/000037
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:

20 FEB 2020

To,
M/s. Hetero Labs Ltd.,
Hetero Corporate, 7-2-A2, Industrial Estates,
Sanathnagar, Hyderabad-500018, Telangana.

Subject: Permission to conduct clinical trial with the FDC of Fimasartan Potassium Trihydrate eq. to Fimasartan Potassium 60mg/120mg + Chlorthalidone IP 12.5mg/12.5mg film coated tablet (Vide protocol no. HCR/III/FICHEH/01/2019, version no. 1.0, dated: 24.01.2019)-regarding.

Dear Sir,

With reference to your letter No. nil dated 08.04.2019 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-Drugs/58/2019 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;
- III. 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;
- IV. 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;

- V. 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;
- VI. 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;
- VII. 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;
- VIII. 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;
- IX. 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;
- X. 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 electronically in the SUGAM portal;
- XI. 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;
- XII. 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;
- XIII. 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;
- XIV. 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;
- XV. 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;
- XVI. where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;
- XVII. 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing Authority;
- XVIII. 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;
- XIX. the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- XX. **Under inclusion criteria the maximum limit of diastolic BP should be revised to ≤ 110 mm Hg and systolic BP should be revised to ≤ 180 mm Hg.**
- XXI. **Biochemical tests should also be performed at 2 week of the study.**
- XXII. **Firm should submit copy of Form 46A for the Fimasartan Potassium Trihydrate API to this Directorate.**
- XXIII. **Firm should submit analytical method validation report for microbial test to this Directorate for review.**

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/58/2019

1. The Central Licensing Authority hereby permits **M/s. Hetero Labs Ltd., Hetero Corporate, 7-2-A2, Industrial Estates, Sanathnagar, Hyderabad-500018, Telangana** (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 **HCR/III/FICHEH/01/2019, version no. 1.0, dated: 24.01.2019** 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:

20 FEB 2020

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Fimasartan Potassium Trihydrate eq. to Fimasartan Potassium 60mg/120mg + Chlorthalidone IP 12.5mg/12.5mg film coated tablet
Therapeutic class:	Angiotensin II antagonists & diuretic
Dosage form:	Film Coated Tablet
Composition:	Fimasartan Potassium Trihydrate eq. to Fimasartan Potassium 60mg/120mg + Chlorthalidone IP 12.5mg/12.5mg film coated tablet
Indications:	For the treatment of 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


 Central Licensing 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-A

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No	EC Registration Number
1	Dr. D. Anil kumar MBBS, MD (General Medicine)	Department of Medicine, In Patient Block, 2 nd Floor Gandhi Hospital, Musheerabad, Secunderabad, Telangana-50000	Institutional Ethics Committee, Gandhi Medical College, Musheerabad, Secunderabad, Telangana-500003	ECR/180/Inst/API/ 2013/RR-16
2	Dr. SK. Noushad Ali MBBS,MD (General Medicine)	ACSR Government Medical College & Hospital, Dargamitta, Nellore-524004	Institutional Ethics Committee, ACSR Government Medical College & Hospital, Dargamitta, Nellore -524004	ECR/961/Inst/API/ 2017
3	Dr. Deo Nidhi Mishra MBBS,MD (Medicine)	Nirmal Hospital Campus Opp.MLB Medical College, Gate No.3 Jhansi(U.P)-284128	Institutional Ethics Committee, Nirmal Hospital Institutional Ethics Committee, Nirmal Hospital Campus, Opp.MLB Medical College gate no.3 Kanpur Road,Jhansi-284128 (U.P)	ECR/325/Inst/UP/ 2013/RR-16
4	Dr. Kancharla Sudhakar MBBS, MD (General Medicine)	New Govt. General Hospital, (Associated By Govt. Siddhartha Medical College) Govt. Siddhartha Medical College Campus, Gunadala, Vijayawada- 520008, Andhra Pradesh.	Institutional Ethics Committee Siddhartha Medical College & Govt. General Hospital(IEC SMC & GGH) Govt. Siddhartha Medical College Campus, Gunadala, Vijayawada-520008, Andhra Pradesh.	ECR/633/Inst/API/ 2014/RR-17
5	Dr. Swapnav Borthakur MBBS, MD (Medicine)	Down Town Hospital, Dispur, G.S. Road, Guwahati-781006	Ethics Committee Down Town Hospital, Dispur, G.S. Road, Guwahati-781006	ECR/549/Inst/AS/ 2014-RR-17
6	Dr. Rathod Bharatsingh Deorao MBBS, MD (Medicine)	OPD 20, Old Building, Department of General Medicine, Grant Government Hospital and Sir JJ Group of Hospitals, Byculla, Mumbai- 400008	Institutional Ethics Committee Department of Pharmacology, Grant Government Medical College, Byculla, Mumbai -400008	ECR/382 /MH/INST/RR- 2016
7	Dr. Sohan Kumar Sharma MBBS,MD (General Medicine) D.M.(Cardiology)	Department of Cardiology Ground floor G -2, Dhanvantri OPD Block SMS Hospital Jaipur-302004	Office of Ethics Committee SMS Medical College & Attached Hospitals, Jaipur, First Floor ,Dhanvantri OPD Block SMS Hospital ,JLN Marg Jaipur- 302004,Rajasthan.	ECR/26/Inst/RJ /2013/RR-16

Place:
Date: **20 FEB 2020**


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