

9012/16.07.19

File No. FDC/MA/19/000051 ✓  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(FDC Division)

Tele. No.: 011-23236965  
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FDA Bhawan, Kotla Road  
New Delhi-110002

Dated:

To,

M/s. Cipla Limited,  
Lower Parel, Mumbai-400013.

05 AUG 2019

**Subject:** Permission for conducting Clinical Trial with FDC of Fluticasone Propionate 100mcg + Salmeterol 50mcg inhalation powder (Dry powder inhaler) (Vide Protocol No. CRD/31 and CRD/34, Version No. 2.0, dated 27.06.2019) for export purpose-regarding.

Dear Sir,

With reference to your letter No. CIPLA/DCG(I)/181/2019 dated 16.07.2019 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-Drugs/70/2019 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. S. Eswara Reddy)  
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 another Ethics Committee for the protocol for conduct of the clinical trial at the same site.
- IV. The Central Licensing 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 Licensing 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 Licensing Authority.
- IX. In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing 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 Licensing 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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 Licensing 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 --

**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/70/2019

1. The Central Licencing Authority hereby permits **M/s. Cipla Limited, Lower Parel, Mumbai-400013** (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 **CRD/31 and CRD/34, Version No. 2.0, dated 27.06.2019 for export purpose** 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: .....

**05 AUG 2019**

  
 Central Licencing Authority  
 Stamp

Director General of Health Services  
 Dte. General of Health Services  
 Ministry of Health and Family Welfare  
 FDA Bhamburda, Kalla Road, L.T.O.  
 New Delhi-110002

**Annexure:**

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Fluticasone Propionate 100mcg + Salmeterol 50mcg inhalation powder (Dry powder inhaler)
Therapeutic class:	Respiratory
Dosage form:	Dry Powder Inhaler
Composition:	Fluticasone Propionate 100mcg + Salmeterol 50mcg inhalation powder (Dry powder inhaler)
Indications:	For the treatment of asthma

**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

Sr. No.	Investigator & Trial site	Ethics Committee Name/Registration Number
1.	Dr. Goyal Ashish Omprakash, Medipoint Hospital Pvt. Ltd., 241/1, New D. P. Road, Aundh-Baner Boundry, Baner, Pune-411007.	Penta Med Ethics Committee, Medipoint Hospital Pvt. Ltd., 241/1, New D. P. Road, Aundh, Pune-411007. ECR/357/Inst/MH/2013/RR-16
2.	Dr. Nikalje Rajkumar Gautam, Lifepoint Multispeciality Hospital, 145/1, Mumbai Bangalore Highway, Hotel Sayajii Wakad, Pune-411057.	Lifepoint Research Ethics Committee, 145/1, Mumbai Bangalore Highway, Hotel Sayajii Wakad, Pune-411057. ECR/751/Inst/MH/2015

Place: .....

Date: .....

05 AUG 2019

05 AUG 2019



Central Licencing Authority

Dr. S. S. S. S.

Stamp

Dt. General of Health Services  
Ministry of Health and Family Welfare  
FDA Bhamburda, Kote Road, I.T.O.  
New Delhi-110022

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