Nil

File No. FDC/MA/20/000119
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:

21 JUN 2021

To,

M/s. Akums Drugs & Pharmaceuticals Ltd.,
19-21, Sector 6A, IIE, SIDCUL, Ranipur,
Haridwar-249403, Uttarakhand.

Subject: **Permission to conduct Phase III clinical trial with the FDC of Montelukast Sodium IP eq. to Montelukast 4mg + Bilastine 10mg orodispersible tablet (Vide protocol no. BRPL/CT/FDC/BIM/12/20, version no. 2.0, dated: 17.03.2021)- regarding.**

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 26.08.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-82/2021** 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;

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-06-82/2021

1. The Central Licencing Authority hereby permits **M/s. Akums Drugs & Pharmaceuticals Ltd., 19-21, Sector 6A, IIE, SIDCUL, Ranipur, Haridwar-249403, Uttarakhand** (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. BRPL/CT/FDC/BIM/12/20, version no. 2.0, dated: 17.03.2021** 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: .....

Date: .....

21 JUN 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:	Montelukast Sodium IP eq. to Montelukast 4mg + Bilastine 10mg orodispersible tablet
Therapeutic class:	Antihistamines
Dosage form:	Tablet
Composition:	Montelukast Sodium IP eq. to Montelukast 4mg + Bilastine 10mg orodispersible tablet
Indications:	For the treatment of Allergic Rhinitis in children aged 6 to 11 years

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.: CT-06-82/2021

S. No.	Name Of Pi	Site Name	Ethics Committee Name, Address & Ec Registration No
1	Dr. Nishikanth Vishnu Tiple	Government Medical College, (Government Hospital) Government Medical College Campus, Chandrapur, Maharashtra -442401 India	Institutional Ethics Committee, GMC, Chandrapur, Government Medical College, Government Medical College Campus, Chandrapur, Maharashtra -442401 India ECR/1155/Inst/MH/2018
2	Dr Atul Jindal	All India Institute Of Medical Sciences, (Government Hospital) Gate No, 1, Great Eastern Rd, Opposite Gurudwara, AIIMS Campus, Tatibandh, Raipur, Chhattisgarh 492099	Institute Ethics Committee, AIIMS Raipur Room No. 2103, 2nd Floor South Wing, Medical College Complex, Gate No. 5, All India Institute Of Medical Sciences, Tatibandh, Ge Road, Raipur, 492099, Chhattisgarh, India ECR/1155/Inst/MH/2018
3	Dr. A.N Gupta	Maharaja Agrasen Hospital (Multispeciality Hospital) Near Metro Station Jain Muni Guru Ramkrishan Marg Block C, Shivaji Park, West Punjabi Bagh, Delhi, 110026	Maharaja Agrasen Hospital Institutional Ethics Committee, R. No -614, 6th Floor Maharaja Agrasen Hospital West Punjabi Bagh, New Delhi ECR/745/Inst/DI/2015/RR-18
4	Dr. Anil Kumar Y.C	Columbia Asia Hospital (Multispeciality Hospital) 85-86, Mysore-Bangalore Ring Road Junction, Bannimantap "A" Layout, Siddiqui Nagar, Mysore-570015	Institutional Ethics Committee, Columbia Asia Hospital Mysore 85-86, Mysore-Bangalore Ring Road Junction, Bannimantap "A" Layout, Siddiqui Nagar, Mysore-570015 ECR/1106/Inst/KA/2018

Place: .....

Date: 21 JUN 2021

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Dr. V. G. SOMANI
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Dte. General of Health Services
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