

Nil

File No. FDC/MA/20/000110 ✓

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Government of India

Directorate General of Health Services

Central Drugs Standard Control Organization

(FDC Division)

FDA Bhawan, Kotla Road

New Delhi-110002

Dated:

To,

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

17 SEP 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Bilastine 10mg Montelukast Sodium IP eq. to Montelukast 4mg oral suspension (Vide protocol no. BRPL/CT/FDC/MIB/03/21, version no. 2.0, dated: 28.06.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on date 31.07.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-150/2021 under the provision of Drugs and Cosmetics Act and Rule. The permission is subject to the conditions mentioned below.

Kindly acknowledge receipt to this letter and its enclosures.

Yours faithfully

V. G.

(Dr. V. G. Soman
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 Licensing 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 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;

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**Permission no.: **CT-06-150/2021**

1. The Central Licencing Authority hereby permits **M/s. Akums Drugs & Pharmaceuticals Ltd., 22, 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/MIB/03/21, version no. 2.0, dated: 28.06.2021**) 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:
17 SEP 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:	Bilastine 10mg + Montelukast Sodium IP eq. to Montelukast 4mg oral suspension
Therapeutic class:	Allergic Rhino Conjunctivitis
Dosage form:	Oral Suspension
Composition:	Bilastine 10mg + Montelukast Sodium IP eq. to Montelukast 4mg oral suspension
Indications:	Indicated 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

Permission no.: CT-06-150/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Paresh A Thakkar MBBS MD (Pediatrics)	Government Medical College & Shri Sayajirao General Hospital (Government Hospital) Sir Sayajirao General Hospital (SSG Hospital), Medical College Baroda, Jail Road (Indira Avenue), Anandpura, Vadodara, Gujarat-390001	Institutional Ethics Committee Of Human RESEARCH Sir Sayajirao General Hospital (SSG Hospital), Medical College Baroda, Jail Road (Indira Avenue), Anandpura, Vadodara, Gujarat-390001
2	Dr Atul Jindal MD DM (Pediatric Critical)	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. Reshu Aggarwal (MBBS, M.D Pediatric)	Puspanjali Hospital & Research Centre Pvt. Ltd. (Multispeciality Hospital) Puspanjali Palace, Delhi Gate, Agra, Uttarpradesh, 282002, INDIA	Puspanjali Hospital Ethics Committee Puspanjali Palace, Delhi Gate, Agra, Uttarpradesh, 282002, INDIA ECR/1235/Inst/UP/2019
4	Dr. Anil Kumar Y.C MBBS, M.D (pediatrics)	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: New Delhi

Date:

17 SEP 2021


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