

Nil

File No. FDC/MA/21/000062
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:

To,

M/s. Mascot Health Series Pvt. Ltd.,
Plot No. 79-80, Sector 6A, IIE SIDCUL,
Haridwar, Uttarakhand-249403.

07 DEC 2021

Subject: Permission to conduct Phase III clinical trial with the FDC of Bilastine 10 mg + Montelukast sodium IP eq. to Montelukast IP 4 mg per 5ml oral suspension(Vide protocol no. MCR/CT/0421/01, version no. 01, dated: 29.06.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 02.03.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. CT-06-189/2021 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;
- 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;

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-06-189/2021**

1. The Central Licencing Authority hereby permits **M/s. Mascot Health Series Pvt. Ltd., Plot No. 79-80, Sector 6A, IIE SIDCUL, Haridwar, Uttarakhand-249403.** (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. MCR/CT/0421/01, version no. 01, dated: 29.06.2021** 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:.....

07 DEC 2021

Annexure:


Central Licencing Authority

Stamp
Dr. V. G. SONANI
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

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 IP 4mg per 5ml oral suspension
Therapeutic class:	Antihistamines
Dosage form:	Suspension
Composition:	Each 5ml oral suspension contains: Bilastine 10mg Montelukast sodium IP eq. to Montelukast 4mg
Indications:	For the treatment of Allergic Rhinitis. It is indicated 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-APermission no.: **CT-06-189/2021**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Ashish Gupta	Brij Medical Centre, 94 E, Near Panki Police Station, Gangaganj Colony, Panki, Kanpur- 208020.	Ethics Committee, Brij Medical Centre, Kanpur- 208020, Uttar Pradesh. ECR/642/Inst/UP/2 014/RR-20
2	Dr. Gaurav Sharma	Vijay Vallabh Hospital and Medical Research Centre, Tirupati Nagar Road, Beside Banjara Hotel, Phase 1, Tirupati Nagar, Virar West, Virar, Maharashtra 401303.	Institutional Ethics committee, Vijay Vallabh Hospital and Medical Research Centre, Maharashtra 401303. ECR/880/Inst/MH/ 2017/RR-20
3	Dr. Jyotsna Seepana	Govt. Medical College and Govt. General Hospital, Srikakulam 532001, A.P., India	Institutional Ethics committee Govt. Medical College and Govt. General Hospital, Srikakulam- 532001, A.P., India. ECR/492/Inst/AP/2013/RR20
4	Dr. Vinay Bajpai	Atmaram Child Care Hospital, Naubasta, Kanpur- 208011, Uttar Pradesh	IEC Prakhar Hospital Pvt. Ltd. Prakhar Hospital Pvt. Ltd 8/219 Arya Nagar, Kanpur, Uttar Pradesh - 208002 India ECR/642/Inst/UP/2 014/RR-20

Place: New Delhi

Date:.....

07 DEC 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.
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