Nil

File No. FDC/MA/20/000197
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 OCT 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 Brinzolamide IP 10mg + Brimonidine Tartrate IP 1mg ophthalmic suspension (Vide protocol no. BRPL/CT/FDC/BNZBR/05/21, version no. 2.0, dated: 07.10.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 26.12.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-173/2021** 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-06-173/2021

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/BNZBR/05/21, version no. 2.0, dated: 07.10.2021** 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: 20 OCT 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:	Brinzolamide IP 10mg + Brimonidine Tartrate IP 1mg ophthalmic suspension
Therapeutic class:	Ophthalmic
Dosage form:	Ophthalmic Suspension
Composition:	Brinzolamide IP 10mg + Brimonidine Tartrate IP 1mg ophthalmic suspension
Indications:	In patients with Primary open-angle glaucoma or ocular 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

Annexure-A.

Permission no.: CT-06-173/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. R S Raman	Maharaja Agrasen Hospital, Block C, Shivaji Park, West Punjabi Bagh, Delhi, 110026	Maharaja Agrasen Hospital Institutional Ethics Committee, (MAH IEC), R. No -614, 6th Floor Maharaja Agrasen Hospital West Punjabi Bagh, New Delhi EC ECR/745/Inst/DL/2015/RR-21
2	Dr. Soumya Ranjan Mahapatra	IMS & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar, Odisha 751003	IEC IMS & SUM Hospital, IMS & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar, Odisha 751003 ECR/627/Inst/OR/2014/RR-20
3	Dr. Rajendra Prakash Maurya	Institute of Medical Sciences, Banaras Hindu University, Varanasi Uttarpradesh-221005	Institutional ethics Committee, Institute of Medical Sciences, Banaras Hindu University, Varanasi Uttarpradesh-221005 ECR/526/Inst/UP/2014/RR-2020
4	Dr. Bhagyajothi B.K	JN Medical College, KLES Dr. Prabhakar Kore Hospital Nehru Nagar, Belagavi10	Institutional Ethics Committee of KILE Academy of Higher Education and Research JNMC Campus, Nehru Nagar, Belagavi-10 Kanataka EC ECR/211/Inst/2013/RR-19
5	Dr. Radkar Pranav Pramod	Lifepoint Multispeciality Hospital 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Waked, Pune-411057, Maharashtra	LPR Ethics Committee 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Waked, Pune- 411057, Maharashtra EC ECR/751/INST/MH/2015/RR-21

Place: New Delhi

Date: .....

20 OCT 2021

Central Licencing Authority

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