NIL

File No.FDC/MA/21/000076
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:

04 OCT 2024

To,

M/s. Alkem Health Sciences,
A Unit of Alkem Laboratories Limited,
Unit-2, Samardung, Karek Block, Namthang,
Sikkim Namthang-737137.

Subject: **Permission to conduct Phase IV clinical trial with the FDC of Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg + Potassium Clavulanate IP eq. to Clavulanic Acid 42.9 mg per 5ml powder for reconstitution into suspension (Vide protocol no. MC/CLV/23-004, version no 1.1, dated 05.01.2024) -regarding.**

Dear Sir,

With reference to manufacturing and marketing permission number MF-270/2021 dated 10.09.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-38/2024** 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. Rajeev Singh Raghuvanshi)
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; 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;

IV. 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;

V. 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;

VI. Status of enrolment of the trial subjects shall be submitted to the Central Licencing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;

VII. Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licencing Authority electronically in the SUGAM portal;

VIII. In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination;

IX. 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 Licencing 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;

X. 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 Licencing Authority within thirty working days of the receipt of order issued by Central Licencing Authority in accordance with the provisions of the said Chapter;

XI. 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 Licencing Authority within thirty working days of receipt of the order issued by the Central Licencing Authority accordance with the provisions of the said Chapter;

XII. The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licencing Authority who may be accompanied by officers of the State Licencing Authority or outside experts as authorised by the Central Licencing 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;

XIII. Where the new drug or investigational new drug is found to be useful in clinical development, the sponsor shall submit an application to the Central Licencing Authority for permission to import or manufacture for sale or for distribution of new drug in India, in accordance with Chapter X of these rules, unless otherwise justified;

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 Licencing Authority may, if considered necessary, impose any other condition in writing with justification, in respect of specific clinical trials, regarding the objective, desig. 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. The formulation intended to be used in the clinical trial study shall be manufactured under GMP conditions using validated procedures.

XVIII. It may kindly be noted that merely granting permission to conduct Clinical trials/Bioavailability or Bioequivalence study with the drug does not convey or imply that, based on the Clinical trial data/ Bioavailability or Bioequivalence study data generated with the drug, permission to market this drug in the country will automatically be granted to you.

XIX. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.

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

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

Permission no.: FDC-CT-06-38/2024

1. The Central Licencing Authority herebypermits **M/s. Alkem Health Sciences,A Unit of Alkem Laboratories Limited, Unit-2, Samardung, Karek Block, Namthang, Sikkim Namthang-737137., Telephone No.: 08016097300, FAX: 08016097300, E-mail:** katkar@alkem.comto conduct clinical trial of the new drug or investigational new drug as perprotocolnumber **(MC/CLV/23-004, version no 1.1, dated 05.01.2024)**in the below mentioned clinical trial sites.
2. Details of new drug or investigational new drug and clinical trial site [As perAnnexure].
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:04 OCT 2024

Central Licencing Authority
Stamp
Dr. RAJEEV SINGH RAGHUVANSHI
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
New Delhi-110002

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg + Potassium Clavulanate IP eq. to Clavulanic Acid 42.9 mg per 5ml powder for reconstitution into suspension
Therapeutic class:	Antibiotic
Dosage form:	Powder for reconstitution suspension
Composition:	Each 5ml reconstitution suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin .... 600mg Potassium Clavulanate IP eq. to Clavulanic Acid .... 42.9 mg
Indications:	It is indicated for short term treatment of paediatric patients with bacterial infections at the following sites when caused by amoxicillin-clavulanate- susceptible organisms: 1. Upper Respiratory Tract Infections (including ENT) e.g. • Acute otitis media (AOM), persistent AOM, or recurrent AOM, typically caused by Streptococcus pneumonia Haemophilusinfluenzae and Moraxella catarrhalis. • Tonsillo-pharyngitis and sinusitis typically caused by StreptococcuspneumoniaHaemophilus Influenza Moraxella catarrhalis and Streptococcus pyogenes. 2. Lower Respiratory Tract Infections e.g. lobar and bronchopneumonia typically caused by Streptococcus pneumonia Haemophilus influenza and Moraxella catarrhalis

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.: FDC-CT-06-38/2024

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1.	Dr.KalpanaDutta	Medical College and Hospital 88, College St, Calcutta Medical College, College Square, Kolkata, West Bengal-700073.	Institutional Ethics Committee for Human Research, Medical College Kolkata, 88, College ST, Kolkata-700073, West Bengal. ECR/287/Inst/WB/2013/RR-19
2.	Dr.MukeshSanklecha	Bombay Hospital & Medical Research Centre 12, VitthaldasThackersey Marg, near Liberty cinema, New Marine Lines, Mumbai, Maharashtra-400020.	Bombay HospitalEthics Committee, Bombay Hospital & Medical Research Centre 12 New Marine Lines, Mumbai, Maharashtra-400020. ECR/296/Inst/MH/2013/RR-20
3.	Dr. M.M.A. Faridi	Eras Lucknow Medical College and Hospital, Sarfarazganj, Hardoi Road, Lucknow-226003.	Institutional ethics Committee, Eras Lucknow Medical College and Hospital, Sarfarazganj, Hardoi Road Lucknow-226003. ECR/717/Inst/UP/2015/RR-21
4.	Dr.JananiSankar	KanchiKamakoti CHILDS Trust Hospital 12 A, Nageswara Rd, Tirumurthy Nagar, Nungambakkam, Chennai, Tamil Nadu-600034.	Ethics Committee of KKCTH and CTMRF, KanchiKamakoti Childs Trust Hospital, 12-A, Nageswara Road, Nungambakkam Chennai, Tamil Nadu-600034. ECR/676/Inst/TN/2014/RR-20

Place: New Delhi

Date: .....

09 OCT 2024

Central Licencing Authority

Dr. RAJEEV SINGH RAGHUVANSHI
Drugs Controller General (India)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India
FDA Bhawan, Kotla Road,
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