File No. FDC/CT/20/000057
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: 27 AUG 2021

To,

M/s. GlaxoSmithKline Pharmaceuticals Ltd.,
Dr. Annie Besant Road, Worli, Mumbai-400030.

Subject: Permission to conduct Phase IV clinical trial with the FDC of Amoxicillin Trihydrate 759.04 mg eq. to Amoxicillin free acid 652.78 mg + Potassium Clavulanate 61.48 mg eq. to Clavulanic acid 50.41mg per 5ml powder for reconstitution into suspension (*652.78mg of amoxicillin free acid is eq. to 600mg amoxicillin with an overfilling of 8.8%. The quantity is adjusted based on purity. In a similar manner the quantity of potassium clavulanate is adjusted based on purity although the potassium clavulanate/silicon dioxide blend ratio is always 1:1. 50.41mg of Clavulanic Acid represents 42.9mg of Clavulanic Acid with an overage of 8% and an overfilling of 8.8%) (Vide protocol no. 213514/Amendment 01, version no. 2.0, dated: 19.05.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-04 on dated 07.09.2020 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-132/2021** 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-06-132/2021

1. The Central Licencing Authority hereby permits **M/s. GlaxoSmithKline Pharmaceuticals Ltd., Dr. Annie Besant Road, Worli, Mumbai-400030.** (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. 213514/Amendment 01, version no. 2.0, dated: 19.05.2021** 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: 27 AUG 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:	Amoxycillin Trihydrate eq. to Amoxycillin free acid + Potassium Clavulanate eq. to Clavulanic acid per 5ml powder for reconstitution into suspension
Therapeutic class:	Antibacterial
Dosage form:	Powder for reconstitution into oral suspension
Composition:	Amoxicillin Trihydrate 759.04 mg eq. to Amoxicillin free acid 652.78 mg* + Potassium Clavulanate 61.48 mg eq. to Clavulanic acid 50.41mg per 5ml powder for reconstitution into suspension **(*652.78mg of amoxicillin free acid is eq. to 600mg amoxicillin with an overfilling of 8.8%. The quantity is adjusted based on purity. In a similar manner the quantity of potassium clavulanate is adjusted based on purity although the potassium clavulanate/silicon dioxide blend ratio is always 1:1. 50.41mg of Clavulanic Acid represents 42.9mg of Clavulanic Acid with an overage of 8% and an overfilling of 8.8%).**
Indications:	As per approved protocol

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-06-132/2021

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr. Sreenivas V	St. John's Medical College Hospital, Sarjapur Road, Bangalore-540034	St. John's Medical College Hospital, Sarjapur Road, Koramangala, Bangalore-540034, Karnataka ECR/238/Inst/KA/2013/RR-19
2	Dr. Vikas Malhotra	Dept of ENT, 3 Floor, B.L. Taneja Block, Maulana Azad Medical College, Bahadurshah Zafar Marg, New Delhi-110002	Intuitional Ethics Committee, 3rd Floor, Room No. 306B, Maulana Azad Medical College, Bahadurshah Zafar Marg, New Delhi-110002 ECR/329/Inst/DL/2013

Place: New Delhi

Date: .....

27 AUG 2021

Central Licencing Authority

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Dr. V. G. SOMANI
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Ministry of Health and Family Welfare
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