

Nil

File No. FDC/MA/21/000160 ✓
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:

11 3 SEP 2021

To,

M/s. Zydus Healthcare Ltd.,
Zydus Corporate Park,
Scheme No. 63, Survey No. 536,
Khoraj (Gandhinagar), Nr, Vaishnodevi Circle,
S.G. Highway, Ahmedabad-382481, Gujarat, India.

Subject: Permission to conduct Phase III clinical trial with the FDC of Indacate Maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg per actuation delivers metered dose inhaler (Vide protocol no. 21-07, version no. 00, dated 15.07.2021)-regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 19.07.2021 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **CT-06-147/2021** 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 faithful



(Dr. V. G. Somai)
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, 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;

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-06-147/2021**

1. The Central Licencing Authority hereby permits **M/s. Zydus Healthcare Ltd. Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khora (Gandhinagar), Nr, Vaishnodevi Circle, S.G. Highway, Ahmedabad-382481 Gujarat, India.** (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. 21-07, version no. 00, dated: 15.07.2021** 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:

Annexure: **13 SEP 2021**

Central Licencing Authority

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

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Indacaterol Maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg per actuation delivers metered dose inhaler
Therapeutic class:	Corticosteroid and Bronchodilator
Dosage form:	Inhaler (Metered Dose Inhaler)
Composition:	Indacaterol Maleate eq. to Indacaterol 75mcg + Budesonide IP 200mcg per actuation delivers metered dose inhaler
Indications:	In patients with chronic obstructive pulmonary disease

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-06-147/2021**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1	Dr Neeraj Gupta	Professor & Head, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan (ECR/1156/Inst/RJ/2018)
2	Dr Manish Kumar Jain	Consultant Pulmonologist Maharaja Agrasen Superspeciality Hospital, Central Spine Sector No. - 7 Vidhyadhar Nagar, Jaipur, Rajasthan-302039	IEC Maharaja Agrasen Hospital situated at Maharaja Agrasen Superspeciality Hospital Central Spine Agrasen Aspatal Marg Sector 7 Vidhyadhar Nagar Jaipur, Rajasthan (ECR/1222/Inst/RJ/2019)
3	Dr. Gautam S	Consultant Pulmonologist, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi (Belgaum) – 590002, Karnataka	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi– 590002, Karnataka (ECR/1242/Inst/KA/2019)
4	Dr. Nikalje Rajkumar Gautam	Consultant Pulmonologist Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India.	LPR Ethics Committee, Lifepoint Multispecialty Hospital, 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Wakad, Pune 411057, Maharashtra, India (ECR/751/Inst/MH/2015/RR-21)
5	Dr. Sarat Kumar Behera	Consultant Pulmonologist, Hi-Tech Medical College and Hospital, Health Park Pandara, Rasulgarh, Bhubaneswar, Khordha, Orissa-751025	Institutional Ethics Committee, Hi-Tech Medical College and Hospital, Health Park Pandara, Rasulgarh, Bhubaneswar, Khordha, Orissa-751025 (ECR/273/Inst/OR/2013/RR-20)

Place: New Delhi**Date:****Central Licencing Authority****Stamp**