

NIL

File No.FDC/CT/23/000091
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. Lupin Limited,
4th Mile, Bhasmey, Karmarey-Bhasmey Block,
Duga Ilaka, East Sikkim, Sikkim-737132.

20 MAR 2024


Subject: Permission to conduct Phase IV clinical trial with the FDC of Fluticasone Furoate 100mcg + Glycopyrronium Bromide Ph. Eur eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg Inhalation Powder in Capsule (Vide protocol no. CT/23/004, Version no. Final 00, dated 19.12.2023) -regarding.

Dear Sir,

With reference to your online application submitted in Form CT-04 on dated 26.12.2023 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. FDC-CT-06-17/2024 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

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.: **FDC-CT-06-17/2024**

1. The Central Licencing Authority hereby permits **M/s. Lupin Limited, 4th Mile, Bhasmey, Karmarey-Bhasmey Block, Duga Ilaka, East Sikkim, Sikkim-737132 Telephone No. 7363046817, Fax No. 0112341913, E-mail: kuldeepwakhloo@lupin.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number (**CT/23/004, Version no. Final 00, dated 19.12.2023**) 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: 2024

Annexure:

Details of new drug or investigational new drug:


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 (India)

Names of the new drug or investigational new drug:	Fluticasone Furoate 100mcg + Glycopyrronium Bromide Ph. Eur eq. to Glycopyrronium 50mcg + Vilanterol Trifenatate eq. to Vilanterol 25mcg Inhalation Powder in Capsule
Therapeutic class:	Bronchodilators
Dosage form:	Inhalation Powder
Composition:	Each capsule contains: Fluticasone Furoate 100mcg Glycopyrronium Bromide Ph. Eur eq. to Glycopyrronium 50mcg Vilanterol Trifenatate eq. to Vilanterol 25mcg
Indications:	Maintenance treatment of patients with moderate to severe COPD

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.: **FDC-CT-06-17/2024**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1.	Dr Namrata Modi	Life Care Hospital Lekha Nagar, New Nashik, Mumbai, Agra Highway, Nashik, Maharashtra 422009.	Muktai Hospital Institutional Ethics Committee, Muktai Hospital, Plot No 11, Shivaji Nagar, Nashik Maharashtra 422006. ECR/251/Inst/Maha/2013/RR19
2.	Dr Ashish Kumar Jaiswal	Ajanta Research Centre Ajanta Research Centre, Ajanta Hospital & IVF center, 765, ABC complex, kanpur Road, Alambagh, Lucknow 226005.	IEC Ajanta Hospital & IVF Centre, Ajanta Hospital and IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow Uttar Pradesh 226005 India. ECR/611/Inst/UP/2014/RR-20
3.	Dr Varade Deepak Bhanudas	Shree Ashirwad Hospital Shree Ashirwad Hospital, C/3 Shree Complex, Opposite to Mahavir Nagar, Manpada Road, Dombivli-East, Mumbai Maharashtra 421201.	Altezza Institutional Ethics Committee, Shree Ashirwad Hospital, C/3 Shree Complex, Opposite Mahavi Road, Manpada Road, Dombivli, Thane, Maharashtra 421201 India. ECR/1457/Inst/MH/2020
4.	Dr Vaghani Mahesh	Global Hospital Global Hospital, OPD 1, 4th floor, Besides Navjivan, Sarthana, Jakatnaka, Surat 395006.	Global Ethics Committee, Room Number 110, 4th Floor, Global Hospital, Sarthana Jakatnaka Surat, Gujarat 395006 India. ECR/1616/Inst/GJ/2021
5.	Dr Maulesh Tailor	Divine Multispecialty Hospital Divine Multispecialty Hospital, 2nd & 3rd floor, Shikshapatri Sky Court, Near Swagat Flamingo, Sargasan, Gandhinagar 382421.	Divine Ethics Committee, Divine Multispecialty Hospital, 2nd -3rd Floor, Shikshapatri Sky Couart, Near Swagat Flamingo, Sargasan, Gandhinagar, Gandhinagar Gujarat 382421 India. ECR/1731/Inst/GJ/2022
6.	Dr Anand Yannawar	Sangvi Multi-specialty Hospital Sangvi Multi Specialty Hospital, Sr No 71/1/2/189, Krushna Chowk, New Sangvi, Pune Maharashtra 411027.	IEC-Sangvi Multispeciality Hospital Sangvi Multispeciality Hospital, S. No 71/1/2/189, C.S 2387 Krushna Chowk, Krishna Nagar, New Sangvi Pune, Maharashtra 411027. ECR/1865/Inst/MH/2023

Place: New Delhi

Date:

08 MAR 2024

**Central Licensing Authority**

Dr. RAJEEV SINGH BAGHUVANSHI
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 (India)