

Nil

File No. FDC/MA/25/000036
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: 25-Jul-2025

To,

M/s. Lupin Ltd.,
EPIP, SIDCO, Industrial Complex,
Kartholi, Bari Brahmana, Jammu,
J & K-181133, India.

Subject: Permission to conduct Phase III clinical trial with the FDC of Glycopyrronium, Formoterol Fumarate Dihydrate and Fluticasone Propionate Inhalation (12.5mcg + 6mcg + 125mcg) (Vide protocol no. CT/24/010, version no. Final 00, dated 29.01.2025) - regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 25.02.2025 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-30/2025** 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,
RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

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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;
- V. 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;

- VI. 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;
- VII. 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;
- VIII. 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;
- IX. 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;
- X. 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;
- XI. 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;
- XII. 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 in accordance with the provisions of the said Chapter;
- XIII. 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;
- XIV. 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;
- XV. 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;
- XVI. 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, design, subject population, subject eligibility, assessment, conduct and treatment of such specific clinical trial;
- XVII. The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- XVIII. The formulation intended to be used in the clinical trial study shall be manufactured under GMP conditions using validated procedures.
- XIX. 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.
- XX. **The firm should submit Phase III clinical trial report to CDSCO for further review by the committee.**

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-06-30/2025**

1. The Central Licencing Authority hereby permits **M/s. Lupin Ltd., EPIP, SIDCO, Industrial Complex, Kartholi, Bari Brahmana, Jammu, J & K-181133, India., Telephone no. 91-1923-220046, Fax no. 91-1923-220177, Email ID: kuldeepwakhloo@lupin.com** to conduct clinical trial of the new drug or investigational new drug as per protocol number **(Vide protocol no. CT/24/010, version no. Final 00, dated 29.01.2025)** 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.

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Central Licencing Authority

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Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Glycopyrronium, Formoterol Fumarate Dihydrate and Fluticasone Propionate Inhalation (12.5mcg + 6mcg + 125mcg)
Therapeutic class:	LAMA LABA ICS
Dosage form:	Meter Dose Inhaler
Composition:	Each actuation delivers: Glycopyrronium Bromide Ph. Eur. 12.5mcg Equivalent to Glycopyrronium 6mcg Formoterol Fumarate Dihydrate IP 125mcg Fluticasone Propionate IP
Indications:	Maintenance treatment of patients with 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-A**Permission no.: FDC-CT-06-30/2025**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No
1.	Dr. Himanshu Prophale	Ace Hospital and Research Center 32/2 A, Gulwani Maharaj Road, Erandwane, Pune, Maharashtra- 411004	Institutional Ethics Committee ACE Hospital, ACE Hospital and Research Centre, 32/2 A, Gulwani Maharaj Road, Erandwane, Pune, Maharashtra- 411004 ECR/1836/Inst/MH/2023
2.	Dr. Sushama Dugad	Supe Heart and Diabetes Hospital and Research Centre, Opposite Adharashram, Gharpure Ghat, Near Rungtha School, Ashok Stambh, Nashik 422002	Supe Hospital Ethics Committee Supe Heart and Diabetes Hospital and Research Centre, Opposite Adharashram, Gharpure Ghat, Near Rungtha School, Ashok Stambh, Nashik 422002 ECR/272/Inst/MH/2013/RR-24
3.	Dr. Jayesh Ambaliya	Divine Multispeciality Hospital 2 nd -3 rd floor, Shikshapatri sky court, Near Swagat flamingo, Sargasan, Gandhinagar, Gujarat- 382421	Divine Multispeciality Hospital 2 nd -3 rd floor, Shikshapatri sky court, Near Swagat flamingo, Sargasan, Gandhinagar, Gujarat- 382421 ECR/1731/Inst/GJ/2022
4.	Dr. Rajkumar Nikalje	Sr. No. 145, Multispecialist Hospital in Wakad, PCMC, 1, Mumbai Pune Bypass Rd, Near Sayaji Hotel, Wakad, Pimpri- Chinchwad Maharashtra -411057	LPR Ethics Committee Sr. No. 145, Sr. No. 145, Multispecialist Hospital in Wakad, PCMC, 1, Mumbai Pune Bypass Rd, Near Sayaji Hotel, Wakad, Pimpri- Chinchwad Maharashtra -411057 ECR/75/Inst/MH/2015/RR-21
5.	Dr. Deepak Varde	Shree Ashirwad Hospital, A-1 Manpada Rd. Purva Society, Manpada Rd, Purva Society, Gograswadi, Dombivli East, Dombivli- 421201	Altezza Institutional Ethics Committee Shree Ashirwad Hospital, A-1 Manpada Rd. Purva Society, Manpada Rd, Purva Society, Gograswadi, Dombivli East, Dombivli- 421201 ECR/1475/Inst/MH/2020
6.	Dr. Mahesh Vaghani	Global Hospital 1, 4 th Floor, Beside Navjivan Sarthana Jakatnaka, Surat, Gujarat- 395006	Global Ethics Committee, Global Hospital 1, 4 th Floor, Beside Navjivan Sarthana Jakatnaka, Surat, Gujarat- 395006

			ECR/1616/Inst/GJ/2021
7.	Dr. Ashish Goyal	Orchid Hospital 2 nd Floor, L-Square, Porwal Road, Sr No-282/3/3 off. Dhanori, Jakat Naka, Lohagaon, Pune, Maharashtra-411047	Orchid Speciality Hospital Ethics Committee, Orchid Speciality Hospital 2 nd Floor, L-Square, Porwal Road, Sr No-282/3/3 off. Dhanori, Jakat Naka, Lohagaon, Pune, Maharashtra-411047 ECR/1089/Inst/MH/2018/RR-21
8.	Dr. Abhijit Telkhade	Shivam Hospital Plot No. 57, C.R.W. CHS, Kalyan Rd, near M.I.D.C. Water Tank, Dombivli East, Dombivli, 421203	Altezza Institutional Ethics Committee Shree Ashirwad hospital, C/3 Shree Complex opp. To Mahavir Nagar, Manpada Road, Dombivli, Maharashtra, 421201 ECR/1457/Inst/MH/2020
9.	Dr MK Pal	Janta Hospital and Maternity Centre Near Water Head tank, Amara- Akhari bypass Chunar Road, Varanasi, Uttar Pradesh 221011	Janta Hospital Ethics Committee, Janta Hospital and Maternity Centre Near Water Head tank, Amara-Akhari bypass Chunar Road, Varanasi, Uttar Pradesh 221011 ECR/839/Inst/UP/2016/RR-19
10.	Dr. Shreehas Badrapurkar	Ishwar Institute of Health care Ishwar Height, 1 st Floor, plot no. 7, gut no 6/1, beside Punjabi Bhavan, Padegaon, Aurangabad, Maharashtra-431002	Ethics Committee of Ishwar Institute of Health care Ishwar Height, 1 st Floor, plot no. 7, gut no 6/1, beside Punjabi Bhavan, Padegaon, Aurangabad, Maharashtra- 431002 ECR/988/Inst/MH/2017/RR-20
11.	Dr. Manish Kumar Jain	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan.	IEC Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Rajasthan - 302039 ECR/1222/Inst/RJ/2019/RR22
12.	Dr. Ashish Nikhare	Lata Mangeshkar Hospital, YMCA Complex, Maharajbagh Rd, Sitabuldi, Nagpur Maharashtra- 440012	Institutional Ethics Committee NKP Salve Institute of Medical Sciences Digdoh Hills, Hingna Road Nagpur Maharashtra- 440019 ECR/88/Inst/MH/2013/RR-24
13.	Dr. Raghavendra Reddy	Renova Neelima Hospitals Voltas Company Pvt Ltd, Opp:, 7-2-1735, Sanath Nagar Main	Institutional Ethics Committee- Renova Neelima Hospitals Voltas Company Pvt Ltd, Opp:, 7-2-1735, Sanath Nagar

		Rd, Sanath Nagar, Hyderabad, Telangana- 500018	Main Rd, Sanath Nagar, Hyderabad, Telangana- 500018 ECR/807/Inst/TG/2016/RR-24
14.	Dr. Gaurav Ghatawat	Lion Tarachand Bapa Hospital and Research Centre C.U. Shah Complex, Lion Tarachand Bapa Marg, Jian Society, Sion (W) Mumbai, Maharashtra- 400022	Institutional Ethics Committee of Aayush Hospital, 102-1, 1st Floor, Laxman Arcade Vivekanand Co-op Hsg 90 Feet Road Dharavi Mumbai, Mumbai City, Maharashtra-400017 India ECR/1472/Inst/MH/2020
15.	Dr Boyilla Nagaraju	Paarthiv LungCareCentre PlotNo:2, StreetNo.1,Opp:Gokul Theatre, Czech Colony, Sanath Nagar,Hyderabad, Telangana-500018	Ethics Committee— Prime Hospital, Aster Prime Hospital Behind Mythri Vanam Beside Blue Fox Hotel Ameerpet, Hyderabad, Telangana — 500038 ECR/381/Inst/AP/2013/RR-21
16.	Dr Jagdish Rawat	Shri Guru Ram Rai Institute of Medical & Health Sciences and Shri Mahant Indires Hospital	Institutional Ethics Committee-SDRRIM & HS, Admin Block, Shri Guru Ram Rai Institute of Medical & Health Sciences and Shri Mahant Indires Hospital, Patel Nagar, Dehradun, Uttarakhand-248001 ECR/710/Inst/UK/2015/RR-21
17.	Dr Shyam Narain Gupta	Sanjivini Hospital and Research Centre Gomti Nagar, Lucknow, near, Hahnemann Rd, Chauraha, Uttar Pradesh -226010	Sanjivani Lung Centre Ethics Committee 2/4, Vastu Khand, Kathautha Chauraha Beside Fire. Station, Gomti Nagar Lucknow Uttar Pradesh- 226010 ECR/963/Inst/UP/2017/RR-20
18.	Dr Prakash Harishchandra Kurmi	Shivam Hospital, C-4, Satyanarayan Society, Jashodanagar Cross Road, Near Gor No Kuvo, Maninagar East, Ahmedabad	Shivam Ethics Committee Shivam Hospital, C-4, Satyanarayan Society, Jashodanagar Cross Road, Near Gor No Kuvo, Maninagar East, Ahmedabad ECR/63/Inst/GJ/2013/RR-20

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Central Licencing Authority

