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File No. FDC/MA/25/000068
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: 03-Oct-2025

To,

M/s. Glenmark Pharmaceuticals Ltd.,
At M/s Accent Pharma,
Plot No. B-159, 160, 161, 22nd Cross Street,
PIPDIC Industrial Estate, Mettupalayam,
Puducherry- 605009

Subject: Permission to conduct Phase III clinical trial with the FDC of Fluticasone Furoate, Umeclidinium and Vilanterol Dry Powder for Inhalation (200 mcg + 62.5mcg + 25 mcg) (Vide protocol no. GPL/CT/2025/002/III, version no 2.0, dated 23.05.2025)- regarding.

Dear Sir,

With reference to your online application submitted in Form CT-21 on dated 24.03.2025 please find enclosed herewith the "permission to conduct clinical trial study of new drug" bearing no. **FDC-CT-06-41/2025** 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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.

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-06-41/2025**

1. The Central Licencing Authority hereby permits **M/s. Glenmark Pharmaceuticals Ltd., At M/s Accent Pharma, Plot No. B-159, 160, 161, 22nd Cross Street, PIPDIC Industrial Estate, Mettupalayam, Puducherry- 605009, Tel No. 912240189999, Fax No: 912240189988**, to conduct clinical trial of the new drug or investigational new drug as per protocol number **(GPL/CT/2025/002/III, version no 2.0, dated 23.05.2025)** 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

Date: 03-Oct-2025

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Fluticasone Furoate, Umeclidinium and Vilanterol Dry Powder for Inhalation (200 mcg + 62.5mcg + 25 mcg)
Therapeutic class:	Inhaled corticosteroid, as Anticholinergic, and a long- acting beta2- adrenergic agonists.
Dosage form:	Dry Powder for Inhalation
Composition:	Each capsule contains: Fluticasone Furoate Ph. Eur 200 mcg Umeclidinium Bromide equivalent to Umeclidinium 62.5 mcg Vilanterol Trifenatate equivalent to Vilanterol 25mcg
Indications:	Indicated for the maintenance treatment of asthma in patients aged 18 year and older.

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

Permission no.: **FDC-CT-06-41/2025**

S. No.	Name of PI	Site Name	Ethics Committee Name, Address & EC registration No.
1.	Dr. Mahesh Kumar	Global Hospital, 4 th Floor, Near Navjivan Restaurant, Sarthana Jakat Naka, Surat, Gujarat- 395006, India	Global Ethics committee, Global Hospital 4 th Floor, Near Navjivan Restaurant, Sarthana Jakat Naka, Surat, Gujarat- 395006, India ECR/1616/INST/GJ/2021
2.	Dr. Sushama Dugad	Supe Heart and Diabetes Hospital and Research Centre, Opposite Adhar Ashram, Near Rungtha School, Gharpure Ghat, Ashok Stambh, Nashik, Maharashtra-422002	Supe Hospital Ethics Committee Supe Heart and Diabetes Hospital and Research Centre, Opposite Adhar Ashram, Near Rungtha School, Gharpure Ghat, Ashok Stambh, Nashik, Maharashtra-422002 ECR/272/Inst/MH/2013/RR-24
3.	Dr. Sandeep Katiyar	Apollo Spectra Hospital (Apollo Speciality Hospital Pvt. Ltd.), 14/138, Chunni Ganj, Kanpur- 208001, Uttar Pradesh, India.	Apollo Speciality Hospital, Kanpur Ethics Committee, Apollo Speciality Hospital Pvt. Ltd. 14/138, Chunni Ganj, Kanpur-208001, Uttar Pradesh, India ECR/1327/INST/UP/2019/RR-24
4.	Dr. Manish Kumar Jain	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan. India	IEC, Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector- 7, Vidhyadhar Nagar, Jaipur Rajasthan- 302039, India ECR/1222/Inst/RJ/2019/RR-22
5.	Dr. Sanjay Verma	GSVM Medical College, Department of Respiratory Medicine, Swaroop Nagar, Kanpur- 208002, Uttar Pradesh, India	Ethics Committee, Room No. 125, 1 st Floor, GSVM Medical Medical College, Swarioo Nagar, Kanpur-208002, Uttar Pradesh. ECR/680/Inst/UP/2014/RR-20
6.	Dr. Ashish Nikhare	Lata Mangeshkar Multispeciality Hospital, 5, Near YMCA Complex, Maharajbagh Road, Sitabuldi, Nagpur-440012, Maharashtra.	Institutional Ethics Committee NKP Salve Institute of Medical Sciences and Research Centre, Lata Mangeshkar Multispeciality Hospital, Digdoh Hills, Hingna Road Nagpur – 440019, Maharashtra. ECR/88/Inst/MH/2013/RR-24
7.	Dr. Shashi Bhushan L P	Victoria Hospital, BMCRI, KR Road, Fort Bengalore-560002, Karnataka, India	Ethics Committee of BMCRI, Bangalore Medical College and Research Institute, KR Road Fort, Benglore - 560002 ECR/302/Inst/KA/2013/RR-20
8.	Dr. Akash Balki	Shree Hospital and Critical Care Centre, 799 Om Nagar, Opp Tajshree Building, Sakkardar Sq., Nagpur-440009.	Shree Hospital Ethics Committee Shree Hospital Unit, Plot No.786 A, 3rd Floor Behind Shree Hospital & Critical Care Centre, Mirchi Bazaar, Umrer Road, Sakkardara, Sq, Nagpur-440009, India. ECR/553/Inst/MH/2014/RR-20

9.	Dr. Keyur Brahme	Department of Medicine, Sir Sayajirao General (S.S.G.) Hospital, Medical College Baroda, Anandpura Jail Road, (Indira Avenue), Vadodara – 390001, Gujarat	Institutional Ethics Committee for Human Research (IECHR), Medical College Baroda, Anandpura, Gujarat Vadodara Gujarat – 390001 India ECR/85/Inst/GJ/2013/RR-24
10.	Dr. Radhey Shyam Chejara	SMS Hospital, Department of Medicine, Dhanvantri OPD Blockc, Ground floor, Room No. 01, SMS Hospital JLN Marg, Jaipur- 302004, Rajasthan, India	Ethics Committee, S.M.S. Medical College, Attached Hospitals, JLN Marg, Jaipur- 302004, Rajasthan, India ECR/26/Inst/RJ/2013/RR-24
11.	Dr. Amitabh Das Shukla	MLN Medical College, Associate with Swaroop Rani Nehru Hospital, Depanment of Pulmonary Medicine, , Prayagraj, Uttar Pradesh- 211002, India.	Institutional Ethics Committee, MLN Medical College Motilal Nehru Medical College, GeorgeTown, Prayaraj, Allahabad Uttar Pradesh -211002 India ECR/922/Inst/UP/2017/RR-22
12.	Dr. Saurabh Karmakar,	All India Institute of Medica Sciences, OPD Building 3 rd Floor, Department of Pulmonary Medicine Patna, Aurangabad Road Phulwari Sharif Patna, Bihar- 801507, India	IEC- AIMS-P, All India Institute of Medica Sciences, Patna Phulwarisharif, Bihar- 801507 ECR/922/Inst/UP/2017/RR-22
13.	Dr. Ram Kaulgud	Karnataka Medical College & Research Institute (KMCRI), Department of General Medicine departmental Research Lab, Room No.-7, Ward No.-304, 3 rd Floor, IPD Block-P, B Road, Vidyanagar, Hubballi-580021, Karnataka, India.	KIMS Ethics Committee, Karnataka Medical College & Research Institute, Office of the Principal Vidyanagar Bubbali, Dharwad Karnataka- 580021, India ECR/486/Inst/KA/2013/RR-20
14	Dr. Santhosh Kumar,	Institute of Chest Diseases & Government Medical College, Chest Hospital Building, Government Medica College Campus, Medical College Entrance Road, Palakottuvayal- 673008, Kozhikode, Kerala.	Institutional Ethics Committee, Govt. Medical College Kozhikode, 4 th Floor, Golden Jubilee Annex Insitutte of Maternal and Child Hearth Kozhikode, Kerala- 673008, India ECR/395/Innst/KL/2013/RR-20
15	Dr. Mahavir Satishchand Bagrecha,	Dr. D.Y. Patil Mdical College, Hospital & Research Centre, Sant Tukaram Nagara Pimpri Pune- 411018 Maharashtra, India	Ethics Committee, Dr. D.Y. Patil Vidhapeth Santa Tukaram Nagar Pimpri PUNE- 411018 ECR/361/Inst/MH/2013-RR-24
16	Dr. Rakhi Ludam,	Institute of Medical Sciences and Sum Hospial, K-8, Kalinga Nagar, ghatikia, Bhubaneshwar- 751003	IEC Ims and Sum Hospital, Institute of Medical Sciences and Sum Hospital, K-8, Kalinga Nagar, Ghatikia, Bhubaneshwar- 751003, Odisha, India ECR/627/Inst/OR/ 2014/RR-20
17	Dr. Sanjay Khatore	Shri Ambe Hospital and Research Institute, 8-9, Jai Karani Nagar, Niwaru Road, Jaipur Rajasthan- 302012 India	Shri Ambe Institutional Ethics Committee, Basement, Shri Ambe Hospital and Research Institute, 8-9, Jai Karani Nagar, Niwaru Road, Jaipur Rajasthan- 302012 India ECR/1557/Inst/RJ/2021

18.	Dr Jagdish Kumar Rawat	Shri Guru Ram Rai Institute of Health & Medical Sciences, Shri Mahant Indresh Hospital Patel Nagar, Dehradun- 248001, Uttarakhand, India	Institutional Ethics Committee-SGRR Institute of Medical & Health Sciences, IEC, Administrative Building, Patel Nagar Dehradun, Uttarakhand-248001 ECR/710/Inst/UK/2015/RR-21
19.	Dr. Himanshu Prophale	ACE Hospital and Research Centre 32/2A, Gulwani Maharaj Road, Erandwane, Pune – 411004, Maharashtra	Institutional Ethics Committee, Ace Hospital, Ace Hospital and Research Centre, 32/2 A, Gulwani Maharaj Road, Erandwane, Pune-411004, Maharashtra, India ECR/1836/Inst/MH/2023
20.	Dr. Shreehas Bardapurkar	Galaxy Superspeciality Hospital, Agnihotra Chowk, Garkheda Area, Ulkanagari, Chhatrapati Sambhaji Nagar, Maharashtra- 431001, India	Ethics Committee of Ishwar Institute of Health Care, 3 rd Floor, Plot no. 7, Gut no 6/1, Padhegaon, Beside Punjabi Bhavan, Jaysingpura, Chhatrapati Sambhaji Nagar, Maharashtra-431002 ECR/988/Inst/MH/2017/RR-20
21.	Dr. Ruchi Dua,	AIIMS Rishikesh, All India Institute of Medical Sciences Rishikesh, Floor no. 6, OPD block, Department of Pulmonary Medicine, Shivaji Nagar, Virbhadra Road, Rishikesh. Uttarakhand- 249201, India	Ethics Committee relating to Clinical Trial, All India Institute of Medical Sciences Rishikesh, Virbhadra Marg, Pashulok, Rishikesh, Dehradun, Uttarakhand- 249203, India ECR/736/Inst/UK/2015/RR-21

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