



सत्यमेव जयते

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL
ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan
ITO, Kotla Road
New Delhi - 110002 (Delhi)
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File No. CT/25/000081

To,

M/s Veeda Clinical Research Limited,
Shivalik Plaza-A Near I.I.M Ambawadi,
Ahmedabad (India) – 380015.

Sir,

With reference to your application No. GCT/CT04/FF/2025/50182 dated 14-Jun-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A randomized, multicenter, multiple-dose, double-blind, placebo-controlled, parallel-group design, clinical endpoint bioequivalence study to evaluate the therapeutic equivalence and safety of fluticasone furoate and vilanterol inhalation powder 100 mcg/25 mcg (Sandoz) and BREO® ELLIPTA® (fluticasone furoate and vilanterol inhalation powder) 100 mcg/25 mcg (GlaxoSmithKline) in adult participants with asthma” Protocol number: SAN-1138 version 1.0 dated 12-Feb-2025 with a total of up-to 1144 subjects from India** under the provisions of New Drugs and Clinical Trial Rules, 2019

The permission granted by the Central Licensing Authority to conduct clinical trial shall be subject to following conditions, namely:-

- (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:

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:

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) Merely granting permission to conduct the **clinical trial** with the Investigational Drug Product does not convey or imply that, based on the **clinical trial study data** generated with the investigational drug, permission to market this drug in the country will automatically be granted to you;

(xix) The permission to initiate clinical trial granted under rule 22 in form CT-06 or automatic approval under rule 23 in Form CT 4A shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority

Stamp

FORM CT-06

(See rules 22,25,26,29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

1. The Central Licensing Authority hereby permits **M/s Veeda Clinical Research Limited, Shivalik Plaza-A Near I.I.M., Ambawadi Ahmedabad (India) - 380015** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number: SAN-1138 version 1.0 dated 12-Feb-2025** in the below mentioned clinical trial sites [As per Annexure].-

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 _____

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority
Stamp

Note: The permission to initiate clinical trial granted under rule 22 in form CT-06 shall remain valid for a period of **two years** from the date of its issue, unless extended by the Central Licencing Authority.

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug	Fluticasone furoate and vilanterol inhalation powder 100mcg/25mcg
Therapeutic class:	Combination inhaled corticosteroid (ICS) and long-acting beta2-adrenergic agonists (LABA)
Dosage form:	Inhalation Powder
Composition:	Fluticasone furoate =100.0000 micrograms (µg) In House Specification Active Vilanterol Trifenatate =25.0000 micrograms (µg) In House Specification Active
Indications:	Indicated for the maintenance treatment of the airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/ or emphysema and to reduce exacerbation of COPD in patients with an exacerbation history

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	N.K.P. Salve Institute of Medical Sciences and Research Centre and Lata Mangeshkar Hospital, Digdoh Hills, Hingna Road Nagpur Maharashtra - 440019	Institutional Ethics Committee, NKP Salve Institute of Medical Sciences Digdoh Hills, Hingna Road, Nagpur- 440019, Maharashtra, India ECR/88/Inst/MH/2013/RR-24	Dr Anil Sontakke
2.	Getwell Hospital and Research Institute, 20/1, Dr. Khare Marg, Dhantoli Nagpur Maharashtra-440012	Getwell Institutional Ethics Committee, Getwell Hospital and Research Institute, 20/1 Dr. Khare Marg, Dhantoli, Nagpur-440012 Maharashtra ECR/109/Inst/Maha/2013/RR-24	Dr Rajesh Nathuram Swarnakar
3.	Charak Hospital and Research center, Hardoi Road, Dubagga Lucknow Uttar Pradesh -226003	IEC Charak Hospital and Research Centre, Charak Hospital and Research Centre, Hardoi Road Dubagga Lucknow- 226003, Uttar Pradesh, India ECR/1255/Inst/UP/2019/RR-24	Dr Rahul Kumar Rathore
4.	Lifepoint Multispecialty Hospital, Sr. No. 145/1, Mumbai Bangalore Highway, Near Hotel Sayaji, Bhumkar Chowk, Wakad Pune-411057, Maharashtra	Lifepoint Research- Ethics Committee, Life Point Mutispecialty Hospital Pvt. Ltd. 145/1, Mumbai-Bangalore highway Near Hotel Sayaji, Wakad, Pune- 411057, Maharashtra, India ECR/751/Inst/MH/2015/RR-21	Dr Rajkumar Gautam Nikalje
5.	Nil Ratan Sircar Medical College and Hospital, 138, Acharya Jagadish Chandra Bose Rd, Sealdah, Raja Bazar Kolkata West Bengal - 700014	Ethics Committee, N.R.S. Medical College, NRS Medical College And Hospital, 138, A.J.C Bose Road Kolkata-700014, West Bengal, India ECR/609/Inst/WB/2014/RR-20	Dr Jaydip Deb
6.	BHS Lakeview Hospital, R.S. No. 73/7, C.T.S. No. 11888, Opp, Fort Lake, Gandhi Nagar Belagavi Karnataka - 590016	BHS Lakeview Hospital, R.S. No 73/7, CTS No: 11888, Opp. Fort Lake, Gandhi Nagar, Belagavi-590016, Karnataka ECR/1586/Inst/KA/2021	Dr Gururaj Mukund Udachankar

7.	Utkal Institute of Medical Sciences and Hospital, Utkal Healthcare Private Limited, Plot No. C/3, Niladri Vihar, CS pur Bhubaneswar Orissa - 751021	Institutional Ethics Committee, Utkal Hospital UIMS And Hospital, A Unit Of UHPL Plot No- C-3, Niladri Vihar Chandrasekharapur, Khordha, Bhubaneswar-751021, Orissa ECR/1920/Inst/OD/2024	Dr Satyajeet Sahoo
8.	Chopda Medicare and Research Centre Pvt Ltd, Magnum Heart Institute, 3/5 Patil Lane No.1, Laxmi Nagar, Near K. B. H Vidyalaya, Canada Corner Nashik Maharashtra - 422005	Magna-care Ethics Committee, Chopda Medicare & Research Centre Pvt Ltd, Magnum Heart Institute, Canada Corner, Nashik 422005, Maharashtra EC/RENEW/INST/2024/16638	Dr Swapnil Suresh Sakhala
9.	S.P. Medical College and A.G. of Hospitals, Research unit, Near Medicine ICU and Maharaja MRI Department of medicine S.P. Medical College and A.G of Hospitals Bikaner Rajasthan - 334001	Ethics Committee, S.P. Medical College, Pawanpuri, Bikaner-334003, Rajasthan, India ECR/27/SP/Inst/RJ/2013/RR-19	Dr Surendra Kumar
10.	MGM Medical College and Hospital, N-6, CIDCO Aurangabad Maharashtra -431003	MGM Ethics Committee for Research On Human Subject, MGM Medical College And Hospital N-6, CIDCO, Aurangabad- 431003, Maharashtra, India ECR/581/Inst/MH/2014/RR-20	Dr Hafiz Mohd Deshmukh
11.	SRM Medical College Hospital and Research Centre, SRM Nagar, Potheri, Kattankulathur Chengalpattu Tamil Nadu -603203	SRM Medical College Hospital and Research Centre, SRM Nagar, Potheri, Kattankulathur, Kancheepuram, Chennai-603203, Tamil Nadu, India ECR/431/Inst/TN/2013/RR-24	Dr Nalini Jayanthi
12.	B. P. Poddar Hospital and Medical Research Limited, 71/1 Humayun Kabir Sarani, New Alipore, Block G Kolkata West Bengal - 700053	BP Poddar And Parvati Devi Foundation for Education 71/1, Humayun Kabir Sarani New Alipore, Block-G, Kolkata-700053, West Bengal, India ECR/1812/Inst/WB/2023	Dr Samadarshi Datta
13.	K.L.E.S. Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar Belagavi Karnataka -	Institutional Ethics Committee, KLE University, KLE Dr. PK Hospital and MRC, Nehru Nagar, Belagavi- 590010, Karnataka, India	Dr Gautam Suresh

	590010	ECR/211/Inst/KA/2013/RR-24	
14.	Sarvodya Hospital, Sector-08 Faridabad Haryana - 121006	Institutional Ethics Committee Sarvodaya Hospital And Research Centre (A Unit Of Anshu Hospitals Limited), YMCA Road, Sector 8, Faridabad -121006, Haryana, India ECR/999/Inst/HR/2017/RR-20	Dr Manisha Mendiratta
15.	Shri Guru Ram Rai Institute of Medical and Health Sciences and Shri Mahant Indiresh Hospital, 4th Floor, South Block, Patal Nagar Dehradun Uttarakhand - 248001	Institutional Ethics Committee SGRR Institute Of Medical Health Sciences IEC, Administrative Building Patel Nagar, Dehradun-248001, Uttarakhand, India ECR/710/Inst/UK/2015/RR-21	Dr Jagdish Kumar Rawat
16.	Sparsh Hospital a unit of Shiva and Shiva Orthopaedic Hospital Pvt Ltd., 146, Infantry Road Bengaluru Karnataka - 560001	Institutional Ethics committee, Sparsh Hospital For Advanced surgeries, No. 146 Opposite Police commissioner Office Infantry Road, Bangalore-560001, Karnataka, India ECR/520/Inst/KA/2014/RR-20	Dr Pooja Bajaj
17.	Jawahar Lal Nehru Medical College, Kala Bagh Ajmer Rajasthan - 305001	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India ECR/1156/Inst/RJ/2018/RR-22	Dr Piyush Arora
18.	Visakha Institute of Medical Sciences, NH-16, Hanumanthavaka Junction Visakhapatnam Andhra Pradesh - 530040	Institutional Ethics Committee, Visakha Institute of Medical Sciences, NH-16, Hanumanthavaka Junction, Visakhapatnam-530040, Andhra Pradesh, India ECR/1421/Inst/AP/2020	Dr Rambabu Konatham
19.	Maratha Vidya Prasarak Samajs, Dr Vasantao Pawar Medical College, Hospital and Research Centre, Vasantdada Nagar, Adgaon Nashik Maharashtra - 422003	IEC, Dr. Vasntaro Pawar Medical College and Hospital, RC Vasantdada Nagar, Adgaon, Nashik-422003, Maharashtra, India ECR/150/Inst/MH/2013/RR-24	Dr Sushama Rikhabchand Dugad

20.	Poona Hospital and Research Center, 27 Sadashiv Peth, Near Alka Talkies, Pune Maharashtra - 411030	Ethics Committee Poona Hospital Research Centre Poona Hospital and Research Centre, 27 Sadashiv peth, Lal Bahadur Shastri Road, Pune-411030, Maharashtra, India ECR/327/Inst/MH/2013/RR-24	Dr Nitin Yashawant Abhyankar
21.	Government Hospital for Chest and Communicable Diseases GHCCD, Pedda Waltair Visakhapatnam Andhra Pradesh - 530017	IEC King George Hospital, King George Hospital, Maharaniipeta, Collector Office Junction, Visakhapatnam-530002, Andhra Pradesh ECR/197/Inst/KGH/2013/RR-20	Dr Chappa Rama Naga Bhushana Rao
22.	Government Fever Hospital Guntur, Dept. of Pulmonary Medicine, Guntur Medical College and General Hospital, Gorantla Guntur Andhra Pradesh - 522001	Ethics Committee GMC and GGH, Guntur Medical College Kannavari, Thota Main Road, Guntur-522004, Andhra Pradesh, India ECR/467/Inst/AP/2013/RR-24	Dr Diyya Sudheer
23.	Government General Hospital, Contonement Vizianagaram Andhra Pradesh - 535003	IEC- Government Medical College, Contonment, Vizianagaram- 535003, Andhra Pradesh, India ECR/1829/Inst/AP/2023	Dr Santosh Kumar Botsa
24.	Government Medical College and Hospital, Bhagya Nagar, 5th Lane Ongole Andhra Pradesh - 523001	Govt. General Hospital and Govt. Medical College, Bhagya Nagar, Ongole Prakasam-523001, Andhra Pradesh, India ECR/1351/Inst/AP/2020	Dr Ranjit Basha P
25.	Kamineni Hospitals Private Limited, L. B. Nagar Hyderabad Telangana - 500068	Kamineni Institutional Ethics Committee Kamineni Hospitals Private Limited, L.B. Nagar, Hyderabad, Ranga Reddy Telangana - 500068 India ECR/58/Inst/AP/2013/RR-24	Dr E. Ravindra Reddy
26.	Swaas Chest Allergy and Sleep Clinic, Katargam Rd, Near SRSS Venus Hospital Road, Lal Darwaja Surat Gujarat - 395003	SIMS Ethics Committee, Surat Institute Of Medical Science, 7/596 597 Pooja Square, Beside Modhvanik Ghanchi, Lal Darwaja, Katargam Road, Surat-395003, Gujarat, India ECR/1811/Inst/GJ/2023	Dr Bhavesh Jivrajbhai Vaghani

27.	Jaipur National University, Institute for Medical Science and Research Center, Jaipur-Agra Bypass, near New RTO office Jaipur Rajasthan -302017	Jaipur National University Institute for Medical Science and Research Center, Jaipur-Agra Bypass, near New RTO office, Jaipur-302017, Rajasthan, India ECR/905/Inst/RJ/2017/RR-20	Dr Rahul Gupta
28.	SDS TRC and Rajiv Gandhi Institute of Chest Diseases (An Institute of Government of Karnataka), 1st Main Road, Near NIMHANS Hospital, Someshwar Nagar Bangalore Karnataka - 560029	Ethics Committee of SDS TRC and RGICD, 1st Floor Administrative Block 1st Main Someshwara Nagar DC Post, Near NIMHANS Campus, Bengaluru- 560029, Karnataka, India ECR/1700/Inst/KA/2022	Dr Akshata J. S
29.	Ishwar Institute of Healthcare, Ishwar Heights, Pl. No. 7, GutNo.6/1, Beside Panjabi Bhavan, Mumbai-Nashik Highway, Padegaon Aurangabad Maharashtra - 431002	Ethics Committee of Ishwar Institute of Health Care, 3rd Floor, Plot No.07, Gut No. 6/1 Padhegaon, Beside Panjabi Bhavan, Jaysingpura, Aurangabad- 431002, Maharashtra, India ECR/988/Inst/MH/2017/RR-20	Dr Shreehas Suhas Bardapurkar
30.	Rajarajeswari Medical College, 202, Kambipura, Mysore Road Bangalore Karnataka - 560074	Institutional Ethics Committee Rajarajeswari Medical College and Hospital No. 202, Kambipura, Mysore Road, Bengaluru- 560074, Karnataka, India ECR/1458/Inst/KA/2024	Dr Archana B
31.	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar Jaipur Rajasthan -302039	IEC, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur-302039 , Rajasthan, India ECR/1222/Inst/RJ/2019/RR-22	Dr Manish Kumar Jain
32.	Apollo Spectra Hospitals, (Apollo Specialty Hospital Pvt. Ltd.), 14/138, Chunni Ganj, Mall Road, Kanpur Uttar Pradesh - 208001	Apollo Specialty Hospitals Kanpur EC, Apollo Specialty Hospitals Pvt. Ltd. 14/138, Chunni Ganj, Kanpur-208001, Uttar Pradesh, India ECR/1327/Inst/UP/2019/RR-24	Dr Sandeep Katiyar

33.	Aster Prime Hospital, Sri Sainatha Multi Speciality Pvt. Ltd. Plot No. 2 and 4, Opp. Passport Seva Kendra, Ameerpet Hyderabad Telangana - 500038	Ethics Committee- Prime Hospital, Aster Prime Hospital, Behind Mythivanam Beside Blue Fox Hotel, Ameerpet, Hyderabad- 500038, Telangana, India ECR/381/Inst/AP/2013/RR-21	Dr Nagaraju Boyilla
34.	Jupiter Hospital and Research Centre, (A Unit of Aatmaj Healthcare Ltd.), Sun Pharma-Atladra Road, Opp. ICAI Bhavan, Atladara Vadodara Gujarat - 390012	Jupiter Hospital and Research Centre, Sun Pharma Atladra Road, Opposite ICAI Bhavan, Atladara , Vadodara- 390012, Gujarat, India ECR/1894/Inst/GJ/2023	Dr Hardik Dinesh kumar Shah
