**File No. CT/168/21-DCG(I)**


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)
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in


सत्यमेव जयते

**File No. CT/21/000168**

To,

M/s Glenmark Pharmaceuticals Ltd.,
B/2, Mahalaxmi Chambers 22, Bhula Bhai,
Desai Road Mumbai (India) – 400026.

Sir,

With reference to your application No. GCT/CT04/FF/2021/29592 (GCT/168/21) dated 16-12-2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44 mcg (Glenmark Pharmaceuticals Ltd) to Flovent HFA (fluticasone propionate inhalation aerosol) 44 mcg (GSK group of companies) in treatment of patients with bronchial asthma" Protocol Number: GLK-2101, Version No. 1.0, dated 13/December/2021** 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) The patients stabilized with dose of more than 250 mcg of Fluticasone should not be included in the study;**

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;
(vi) 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;
(vii) 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;
(viii) 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;
(ix) 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;
(x) 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;
(xi) 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;
(xii) 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;
(xiii) 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;
(xiv) 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;
(xv) 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;
(xvi) 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;
(xvii) 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;
(xviii) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xix) 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;

(xx) 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,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb25574873 2c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca 070507 4b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.06.12 17:55:45 IST

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

**File No. CT/168/21-DCG(I)**

**FORM CT-07**

(See Rules 34, 35, 36, 37 and 38)

**PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OF NEW DRUG OR INVESTIGATIONAL NEW DRUG**

1. The Central Licensing Authority hereby permits **M/s. Glenmark Pharmaceuticals Ltd., Glenmark House, of B2 Mahalaxmi Chambers 22, Bhula Bhai Desai Road Mumbai, (India)-400026** to conduct ~~bioavailability or~~ bioequivalence study of the new drug or investigational new drug as per **Protocol Number: GLK-2101, Version No. 1.0, dated 13/December/2021** in the below mentioned study centre.

2. Details of new drug or investigational new drug and study centre [As per Annexure].

3. This permission is subject to the conditions prescribed in B of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date _____

VENUGOPAL G SOMANI

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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255748732c456d249073e55e953d9cb5b58748ee3113c, postalCode=110002, st=DELHI, serialNumber=e97f241aa0c0bba41522525ffca0705074b4997e6b2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.02.16 12:18:06 +05'30'

(Dr. V. G. Somani)
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 Propionate Inhalation Aerosol USP 44 mcg |
| **Therapeutic class:** | Corticosteroid |
| **Dosage form:** | Inhalation aerosol |
| **Composition:** | Each actuation delivers (ex-actuator)<br>Fluticasone Propionate USP ..... 44 mcg<br>Propellant HFA 134a (1,1,1,2-tetrafluoroethane)..... q.s |
| **Indications:** | Fluticasone Propionate Inhalation Aerosol is an inhaled corticosteroid indicated for: Maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older.<br>Limitations of use: Not indicated for relief of acute bronchospasm |

**Annexure:**

Details of study centre:

| **Names and address of study centre:** | **Ethics committee details** | **Name of principal investigator** |
|---|---|---|
| Hindusthan Hospital, 522/3, 523/3 Nava India Road Udaiyampalayam, Coimbatore - 641028, Tamil Nadu, India | Institutional Human Ethics Committee, Hindusthan Hospital 522/3, 523/3 Nava India Road, Udaiyampalayam, Coimbatore-641028, Tamil Nadu, India<br><br>ECR/1376/Inst/TN/2020 | Dr. Srikanth Krishnamurthy |
| Maharaja Agrasen Superspeciality Hospital, Central Spine, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan, India | IEC Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur-302039, Rajasthan, India<br><br>ECR/1222/Inst/RJ/2019 | Dr. Manish Kumar Jain |
| Shree Hospital & Critical Care Centre, 799, Om Nagar Opp. Tajshree Building Sakkardara Sq.,Nagpur-440009, Maharashtra, India<br><br>Shree Hospital Unit, 785 A, Behind Shree Hospital & Critical Care Centre, Buldtng Mirchi Bazar, Umrer Rd, Omnagar, Sakkardara, Nagpur, 440009, Maharashtra, India | Shree Hospital Ethics Committee, Shree Hospital Unit, Plot No.786 A, 3rd Ftoor Behind Shree Hospital & Critical Care Centre, Mirchi Bazaar, Umrer Road, Sakkardara Sq.,Nagpur-440009, Maharashtra, India<br><br>ECR/553/Inst/MH/2014/RR-20 | Dr. Akash Lataru Balki |
| Orchid Speciality Hospital, Basement-L, Square Porwal Road, Sr. No. 282/3/3, Off, Dhanori, Jakat Naka, Lohgaon, Pune-411047, Maharashtra, India | Orchid Speciality Hospital Ethics Committee, Orchid Speciality Hospital, L, Square Porwal Road, Sr. No. 282/3/3, Lohgaon, Pune-411047, Maharashtra, India<br><br>ECR/1089/Inst/MH/2018/RR-21 | Dr. Ashish Omprakash Goyal |
| 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.<br><br>ECR/751/Inst/MH/2015/RR-21 | Dr. Nikalje Rajkumar Gautam |