



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)  
Phone No.: 91-11-23216367  
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**File No. CT/25/000140**

To,

M/s. Eli Lilly and Company (India) Pvt. Ltd.,  
Plot No. 92, Sector 32, Institutional Area,  
Gurugram, Haryana (India) -122001.

Sir,

With reference to your application No. GCT/CT04/FF/2025/52120 dated 22-Sep-2025, please find enclosed herewith the permission in Form CT-06 for conduct clinical trial titled, **“A Phase 2, Multicenter, Randomized, Double-blind, 52-week Study, to Investigate the Efficacy and Safety of Brenipatide Compared with Placebo for the Treatment of Adult Participants with Uncontrolled Moderate to Severe Asthma” Protocol no.: J2S-MC-GZMR version no. a dated 01-AUG-2025 with a total of up-to 80 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) **Human biological samples i.e. Whole blood, Serum, Plasma, Urine and Nasal tissue related to clinical trial shall be permitted to be exported for analysis subject to the clearance by port offices of CDSCO. Further, ICMR/DHR permission shall be obtained for export of optional biological samples as per DGFT notification number 72/2023 dated 11.03.2024.**
- (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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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,

(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. Eli Lilly and Company (India) Pvt. Ltd, Plot No. 92, Sector 32, Institutional Area, Gurugram, Haryana (India) - 122001 Telephone No.: 1244753000 FAX: 1244753012 E-Mail: IN\_REG@LISTS.LILLY.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: J2S-MC-GZMR version no. a dated 01-AUG-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:

<b>Names of the new drug or investigational new drug</b>	LY3537031
	LY3537031
	LY3537031
	LY3537031
<b>Therapeutic class:</b>	Dual GIPR and GLP 1 RA
	Dual GIPR and GLP 1 RA
	Dual GIPR and GLP 1 RA
	Dual GIPR and GLP 1 RA
<b>Dosage form:</b>	Injection
	Injection
	Injection
	Injection
<b>Composition:</b>	Glycerin U.S.P. Inactive
	L-Histidine Hydrochloride Monohydrate Ph.Eur Inactive

	L-Histidine U.S.P. Inactive LY3537031 =0.6400 milligram (mg) In House Specification Active
	Glycerin U.S.P. Inactive LY3537031 =1.6000 milligram (mg) In House Specification Active
	L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate Ph.Eur Inactive
	Glycerin U.S.P. Inactive L-Histidine Hydrochloride Monohydrate Ph.Eur Inactive
	L-Histidine U.S.P. Inactive LY3537031 =3.1900 milligram (mg) In House Specification Active
	LY3537031 =6.3800 milligram (mg) In House Specification Active
	Glycerin U.S.P. Inactive L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate Ph.Eur Inactive
<b>Indications:</b>	Asthma
	Asthma
	Asthma
	Asthma

#### Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	All India Institute of Medical Sciences, Ethics Committee All India Institute of Medical Sciences situated at Village Sijua, Patrapada, PO Dumduma, Bhubaneshwar Orissa - 751019	Institutional Ethics Committee, Faculty Research, AIIMS Bhubaneswar All India Institute of Medical Sciences, BBSR, AIIMS Bhubaneswar Sijua P/O Patrapada Bhubaneswar Khordha Orissa - 751019 India  ECR/534/Inst/OD/2014/RR-25	Dr Mahismita Patro
2.	All India Institute of Medical Sciences, Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1st Floor, Old O.T. Block, Ansari Nagar, New Delhi Delhi - 110029	Institute Ethics Committee, All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi-110029  ECR/538/Inst/DL/2014/RR-25	Dr Saurabh Mittal
3.	MGM Medical College, Ethics Committee, MGM Medical College, N-6, CIDCO, Aurangabad Maharashtra - 431003	Mahatma Gandhi Mission Ethics Committee for Research on Human Subjects (MGM-ECRHS) Department of Pharmacology, MGM Medical College and Hospital, N-6 CIDCO, Chhatrapati Sambhajnagar (Aurangabad)-431003, Maharashtra, India.	Dr Hafiz Mohd Deshmukh

		ECR/581/Inst/MH/2014/RR-20	
4.	Institute All India Institute of Medical Sciences, Institute Ethics Committee, All India Institute of Medical Sciences, Department of Pharmacology, 2nd Floor, South Wing, Medical College Complex, Gate No.5, Tatibandh, GE Road, Raipur Chhattishgarh - 492099	Institute Ethics Committee, AIIMS Raipur, Room No. 2103, 2nd Floor, South Wing, Medical College Complex, Gate No. 5, All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, Chhattisgarh, 492099, India.  ECR/714/Inst/CT/2015/RR-21	Dr Dibakar Sahu
5.	The Chairman, LPR Lifepoint Multispeciality Hospital Pvt. Ltd., The Chairman, LPR Ethics Committee, Lifepoint Multispeciality Hospital Pvt. Ltd., 145/1, Mumbai-Bangalore Highway, Near Hotel Sayaji, Wakad, Pune Maharashtra - 411057	LPR Ethics Committee Lifepoint Multispeciality Hospital, Sr. No.145/1, Mumbai, Bangalore Highway, Near Hotel Sayaji, Wakad, Pune, 411057, Maharashtra, India.  ECR/751/Inst/MH/2015/RR-21	Dr Rajkumar Nikalje
6.	Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences, Rohtak, 124001, Haryana, India. Rohtak Haryana - 124001	Institutional Ethics Committee, Pt. BO Sharma, Post Graduate Institute of Sciences UHS Rohtak-124001, Haryana, India.  ECR/293/Inst/HR/2013/RR-24	Dr Aman Ahuja
7.	Medstar Speciality Hospital, Kodegehalli Main Road, Sahakarnagar bengaluru Karnataka - 560092	Medstar Speciality Hospital Ethics Committee, Medstar Speciality Hospital, No 641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore Bengaluru (Bangalore) Urban Karnataka-560092  ECR/1324/Inst/KA/2019/RR-24	Dr Hirennappa B Udnur
8.	Aakash Healthcare Super Speciality Hospital, Hospital Plot, Road Number 201, Dwarka Sector-3, Ground floor, Dwarka Delhi Delhi - 110075	Aakash Healthcare Super Specialty Hospital Institutional Ethics Committee Department of Academic & Research, Service Floor, Hospital Plot, Road No. 201, Sector-3 Dwarka, New Delhi-110075, India.  ECR/1265/Inst/DL/2019/RR-24	Dr Akshay Budhreja
9.	Galaxy Superspeciality Hospital and Research Institute, Galaxy Superspeciality Hospital, Research Institute, Agnihotra Chowk, Ulkanagari, Aurangabad, Aurangabad Maharashtra - 431001	Ikon Ethics Committee For Research On Human Subject Ikon Multispeciality Hospital Rose Park H.no.2-7-79, Noor Manzil Majnu Hills Aurangabad, Maharashtra-431001 India.  ECR/I669/Inst/MH/2022	Dr Bardapurkar Shreehas Suhas

10.	Atmaram Child Care and Critical Care, 53, 128, Y Block, Naubasta, Kanpur, Uttar Pradesh, Kanpur Uttar Pradesh - 208011	Ethics Committee Atmaram Child Care and Critical Care53/128, Y Block, Naubasta, Kanpur, Uttar Pradesh, 208011, India.  ECR/1925/Inst/UP/2024	Dr Arjun Bhatnagar
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