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

File No. CT/25/000164

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/2025/53084 dated 17-Nov-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**A Phase 2 Multicenter, Double-Blind, Parallel-Arm Study to Investigate the Efficacy and Safety of Adjunctive Treatment with Brenipatide in Adult Participants with Schizophrenia (RENEW-Scz-1)" Protocol no.: J2S-MC-GZMK amendment no. (a) dated 23-OCT-2025 and amendment no. (b) dated 17-December-2025 with a total of up-to 110 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) "Carcinogenicity study report shall be submitted once the study completed as per commitment in Q4 2027"

(ii) Human biological samples i.e. Whole blood, Serum and Plasma 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.

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) 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;

(ix) 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;

(x) 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;

(xi) 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;

(xii) 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;

(xiii) 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;

(xiv) 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;

(xv) 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;

(xvi) 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;

(xvii) 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;

(xviii) 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;

(xix) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

(xx) 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;

(xxi) 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,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.03.24 17:41:13 +05'30'

(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-GZMK amendment no. (a) dated 23-OCT-2025 and amendment no. (b) dated 17-December-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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2026.03.24 17:41:23 +05'30'

(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	LY3537031
	LY3537031
	LY3537031
	LY3537031
Therapeutic class:	GLP 1 RA
	GLP 1 RA
	GLP 1 RA
	GLP 1 RA
Dosage form:	Injection
	Injection
	Injection
	Injection
Composition:	LY3537031 =0.6400 mg/ml In House Specification Active L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate U.S.P. Inactive
	L-Histidine Hydrochloride Monohydrate U.S.P. Inactive LY3537031 =1.6000 mg/ml In House Specification Active L-Histidine U.S.P. Inactive
	L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate U.S.P. Inactive LY3537031 =3.1900 mg/ml In House Specification Active
	LY3537031 =6.3800 mg/ml In House Specification Active L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate U.S.P. Inactive
Indications:	Schizophrenia
	Schizophrenia
	Schizophrenia
	Schizophrenia

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Dr. D. Y Patil Medical College, Hospital & Research Centre, Sector - 5, Nerul, Navi Mumbai, 400706, Maharashtra, India	Institutional Ethics Committee Hira Mongi Navneet HospitalHira Mongi Navneet Hospital, Mulund West Mumbai, Valaji Ladha Road, Mumbai, Mumbai City, Maharashtra - 400080	Dr Chetan Vispute

		ECR/1793/Inst/MH/2023	
2.	Rajiv Gandhi Government General Hospital, Grand Southern Trunk Road, Near Park Town, Near Chennai Central, Park Town, Chennai, Tamil Nadu, India, 600003	Madras Medical CollegeEVR Periyar Salai Park Town Chennai, Chennai Tamil Nadu, 600003, India ECR/270/Inst/TN/2013/RR-20	Dr Saravana Jothi Ramalingam
3.	Medipoint Hospitals Pvt. Ltd. 241/1, New D. P. Road, Aundh, Pune, Maharashtra, India, 411007.	Pentamed Ethics Committee Medipoint Hospitals Pvt. Ltd., 241/1 New D. P. Road, Near Sai Heritage, Aundh, Pune, Maharashtra, India, 411007 ECR/357/Inst/MH/2013/RR-25	Dr Bhalchandra Kalmegh
4.	All India Institute of Medical Sciences (AIIMS) –Bhopal, AIIMS Campus, Saket Nagar, Habib Ganj, Bhopal, Madhya Pradesh-462020	Institutional Human Ethics Committee All India Institute of Medical Sciences, 2nd Floor, Medical College Building Saket Nagar, Bhopal, Madhya Pradesh -462020 India ECR/775/Inst/MP/2015/RR-21	Dr Tamonud Modak
5.	Lifepoint Multispeciality Hospital, Sr. No. 145/1, Mumbai Banglore Highway, Near Hotel Sayaji, Wakad, Pune, Maharashtra, India, 411057	LPR Ethics Committee Lifepoint Multispeciality Hospital, Sr. No. 145/1, Mumbai Banglore Highway, Near Hotel Sayaji, Wakad, Pune- 411057, Maharashtra, India ECR/751/Inst/MH/2015/RR-21	Dr Nitin Veersingh Dalaya
6.	Dr. Ram Manohar Lohia Institute of Medical Sciences Near Vibhuti Khand, Gomti Nagar, Lucknow, Uttar Pradesh, India, 226010.	Institutional Ethics Committee Dr. Ram Manohar Lohia Institute of Medical Sciences Research Cell Office Room No. 35, 2nd Floor Administrative Block, RMLIMS Lucknow, Uttar Pradesh, 226010, India. ECR/913/Inst/UP/2017/RR-25	Dr Abdul Qadir Jilani
7.	Dharwad Institute of Mental Health and Neurosciences, Dharwad, Dharwad-Belgaum Road, Saidapur, Dharwad, Karnataka, India, 580008	Institutional Ethics Committee Dharwad Institute of Mental Health and Neuro Sciences (IEC DIMHANS), Dharwad Dharwad Institute of Mental Health & Neuro Sciences (DIMHANS) Belagavi Road, Dharwad, Karnataka, India, 580008.	Dr Srinivas Kosgi

		ECR/1610/Inst/KA/2021	
8.	Graphic Era Hospital, 16th Milestone, Chakrata Road, Dehradun, Uttarakhand-248007 India	Institutional Ethics Committee Digestive Disease Centre 2, Ankit Puram, GMS Road Dehradun, Uttarakhand - 248001, India ECR/1671/Inst/UK/2022	Dr Jeetpal Singh Rana
9.	Career Institute of Medical Sciences and Hospital – Lucknow, Near Shalimar Apartment, IIM Road, Lucknow, Ghaila, Uttar Pradesh, India, 226013	IEC Medical Care Centre and Hospital Medical Care Centre and Hospital, Laxmi Complex Kanpur Road, Alambagh, Lucknow Uttar Pradesh-226005 India. ECR/1675/Inst/UP/2022	Dr Abbas Mehdi
10.	Galaxy Superspeciality Hospital & Research Institute, Agnihotra Chowk, Ulkanagari, Aurangabad, Maharashtra, India, 431001	Ethics Committee, Shanti Nursing Home Shanti Nursing Home, Kanchanwadi, Paithan Road, Chh. Sambhajinagar, Maharashtra-431005 ECR/568/Inst/MH/2014/RR-22	Dr. Deshmukh Amol Ashok
11.	Kolhapur Institute of Orthopaedics & Trauma, Near Royal Tourist Hub, New Shahapuri Central, ST Stand Kolhapur-416001, Maharashtra, India	Zenith Institutional Ethics Committee Kolhapur Institute of Orthopaedics & Trauma, Near Royal Tourist Hub, New Shahapuri Central, ST Stand, Kolhapur-416001, Maharashtra, India. ECR/1976/Inst/MH/2024	Dr Shreyansh Patil

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