



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/25/000160

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/2025/52882 dated 07-Nov-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A Phase 2, Multicenter, Randomized, Double-Blind, Parallel-Arm Study to Investigate the Efficacy and Safety of Adjunctive Treatment with Brenipatide in Delaying Time to Relapse Compared with Placebo in Adult Participants with Bipolar Disorder (RENEW-Bipolar-1)”** Protocol no. J2S-MC-GZMJ amendment no. (a) dated 23-OCT-2025 and amendment no. (b) dated 17 December 2025 with a total of up-to 100 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) **More government site shall be included in the study.**
- (ii) **Human biological samples i.e. Whole blood, Serum, Plasma, and Urine 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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
Date: 2026.03.11 09:40:15
+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-GZMJ 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
Date: 2026.03.11 09:40:22
+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
Therapeutic class:	GLP 1 receptor agonist
	GLP 1 receptor agonist
	GLP 1 receptor agonist
Dosage form:	Injection
	Injection
	Injection
Composition:	LY3537031 =0.6400 milligram (mg) Manufacturer Specification Active L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate U.S.P. Inactive Glycerin U.S.P. Inactive
	LY3537031 =1.6000 milligram (mg) Manufacturer Specification Active L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate U.S.P. Inactive Glycerin U.S.P. Inactive
	LY3537031 =3.1900 milligram (mg) Manufacturer Specification Active L-Histidine U.S.P. Inactive L-Histidine Hydrochloride Monohydrate U.S.P. Inactive Glycerin U.S.P. Inactive
Indications:	Bipolar Disorder
	Bipolar Disorder
	Bipolar Disorder

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Institutional Human All India Institute of Medical Sciences, Department of Biochemistry, Institutional Human Ethics Committee, All India Institute of Medical Sciences, Department of Biochemistry Block, Ground Floor, Medical College Building, Saket Nagar, Bhopal Madhya Pradesh - 462024	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

2.	Sowmanasya Hospital, 6, V. N. Nagar, Chinthamani Trichy Tamil Nadu - 620002	Ethics Committee Harshamitra Superspeciality Cancer Centre, No 41 Nachiyar Kovil Street, Woraiyur Tiruchirappalli Tamil Nadu -620003 ECR/926/Inst/TN/2017/RR-20	Dr Gopalakris hnan Ganesan
3.	Institutional Belagavi Institute of Medical Sciences, Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Dr. B. R. Ambedkar Road, Belagavi Karnataka - 590001	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Doctor B R Ambedkar Road, Ayodhya Nagar, Sadashiv Nagar, Belgaum Division, Belagavi, Karnataka, India, 590001 ECR/801/Inst/KA/2016/RR-20	Dr Chandrashekar
4.	Dr. Ram Manohar lohia Institute of Medical Sciences, Research Cell Office Room No. 35 2nd Floor Administrative Block, RMLIMS Lucknow Uttar Pradesh - 226010	Institutional Ethics Committee Dr. Ram Manohar Lohia Institute of Medical Sciences, Research Cell Office Room No. 35, 2nd Floor Administrative Block, RMLIMS Lucknow, U.P 226010, India ECR/913/Inst/UP/2017/RR-25	Dr Abdul Qadir Jilani
5.	Life Point Mutispecialty Hospital Pvt. Ltd., 145/1, Mumbai-Bangalore highway Near Hotel Sayaji Wakad Maharashtra - 411057	LPR Ethics Committee, Lifepoint Multispeciality Hospital, 145/1, Mumbai banglore Highway, Near Hotel Sayaji, Wakad, Pune-411057, Maharashtra, India ECR/751/Inst/MH/2015/RR-21	Dr Dalay Nitin Veersingh
6.	Career Institute of Medical Sciences and Hospital, Department of Psychiatry, IIM Road, Lucknow, Uttar Pradesh, India Lucknow Uttar Pradesh -226020	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
7.	Society for Psychiatric Update and Research, Shanti Nursing Home, Kanchan wadi, Paithan Road, 1st building, 1st floor, Room no. 214, Research department, Chhatrapati Sambhajinagar, Maharashtra, India Sambhajinagar Maharashtra - 431005	Ethics Committee Shanti Nursing Home, Shanti Nursing Home, Kanchanwadi, Paithan Road, Chhatrapati Sambhajinagar (Aurangabad)-431005 EC/568/Inst/MH/2014/RR-22	Dr Chinmay Vinay Barhale

8.	Deva Institute of Healthcare AND Research Pvt Ltd., Department of Psychiatry, Durgakund Road, B 27 70 MN Durgakund, Bhelupura, Varanasi, Uttar Pradesh, India varanasi Uttar Pradesh -221005	DMHC Ethics Committee, Dcap 1st Floor, Deva Institute Of Healthcare Research Pvt. Ltd., Durgakund Road, B 27/70 MN Durgakund, Bhelupura, Varanasi, Uttar Pradesh, India, 221005 EC/2/Inst/UP/2013/RR-24	Dr Venu Gopal Jhanwar
9.	Assured Care Plus Hospital, Department of Psychiatry, Lam Road, 4th, 5th Floor, Star Plus Complex, Near Muktidham Temple Nashik, Opp NMC Divisional Office, Nashik Maharashtra - 422101	Institutional Ethics Committee, Assured Care Plus Hospital, 4th & 5th floor, Star Plus Complex, Lam Road, Near Muktidham Temple, NMC Divisional Office, Nashik Road, Nashik, Maharashtra 422101 ECR/1756/Inst/MH/2022	Dr Nakul Ashok
10.	Galaxy Superspeciality Hospital and Research Institute, Department of Psychiatry, Agnihotra Chowk, Opposite Punjab National Bank, Aurangabad, Maharashtra, India, 431001 Aurangabad Maharashtra - 431001	Ethics Committee of Shanti Nursing Home Shanti Nursing Home, Kanchanwadi, Paithan Road, Aurangabad, Maharashtra –431005, India ECR/568/Inst/MH/2014/RR-22	Dr Deshmukh Amol Ashok
