



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/25/000157**

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/2025/52787 dated 30-Oct-2025, please find enclosed herewith the permission in Form CT-06 for conduct of **phase III** clinical trial titled, **“A Master Protocol for a Randomized, Controlled, Clinical Trial of Multiple Pharmacologic Agents in Adult Participants with Metabolic Dysfunction-Associated Steatotic Liver Disease who are at Increased Risk of Developing Major Adverse Liver Outcomes (SYNERGY-Outcomes)”** Protocol no. N1T-MC-MALO amendment (a) dated **22-SEP-2025 with a total of up-to 280 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) **Interim analysis of safety data shall be submitted to CDSCO every 36 weeks till study duration.**
- (ii) **Independent DSMB (country specific) shall be organized to closely monitor the safety related issues and quarterly report submitted to the Ethics Committee and CDSCO.**
- (iii) **Human biological samples i.e. Whole blood, Serum, Plasma, Urine and Liver 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.**
- (iv) 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;
- (v) 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;

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

(xxi) 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;

(xxii) 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. N1T-MC-MALO amendment (a) dated 22-SEP-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>	LY3298176 (Tirzepatide), LY3437943 (Retatrutid e)
	LY3298176 (Tirzepatide), LY3437943 (Retatrutid e)
	LY3298176 (Tirzepatide), LY3437943 (Retatrutid e)
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	LY3298176 (Tirzepatide), LY3437943 (Retatrutid e)
	LY3298176 (Tirzepatide), LY3437943 (Retatrutid e)
<b>Therapeutic class:</b>	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
<b>Dosage form:</b>	Injection
	Injection
	Injection
	Injection
	Injection
	Injection
	Injection
	Injection
<b>Composition:</b>	LY3298176=5.0000 milligram (mg) In House Specification Active Sodium phosphate dibasic heptahydrate U.S.P. Inactive Sodium chloride U.S.P. Inactive
	LY3298176 =10.0000 milligram (mg) In House Specification Active Sodium phosphate dibasic heptahydrate U.S.P. Inactive Sodium chloride U.S.P. Inactive
	LY3298176=15.0000 milligram (mg) In House Specification Active Sodium phosphate dibasic heptahydrate U.S.P. Inactive Sodium chloride U.S.P. Inactive
	LY3298176=20.0000 milligram (mg) In House Specification Active Sodium phosphate dibasic heptahydrate U.S.P. Inactive Sodium chloride U.S.P. Inactive
	LY3298176 =25.0000 milligram (mg) In House Specification Active Sodium phosphate dibasic heptahydrate U.S.P. Inactive Sodium chloride U.S.P. Inactive
	LY3298176 =30.0000 milligram (mg) In House Specification Active Sodium phosphate dibasic heptahydrate U.S.P. Inactive Sodium chloride U.S.P. Inactive
	LY3437943=4.0000 milligram (mg) In House Specification Active Tris (hydroxymethyl) aminomethan e U.S.P. Inactive Mannitol U.S.P. Inactive
	LY3437943=12.0000 milligram (mg) Any Other Pharmacopia Active Tris (hydroxymethyl) aminomethan e U.S.P. Inactive Mannitol U.S.P. Inactive

<b>Indications:</b>	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver
	Metabolic Disorder, Non-alcoholic Fatty Liver

## Annexure:

Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	Fortis Hospital - Mohali, Sector 62, Phase 8, Fortis Inn, Clinical Research Room, Mon-Fri 10:00-04:00 PM, Mohali, Punjab, India, 160062	Institutional Ethics Committee Fortis hospital Mohali, Sector-62, Phase-8, Mohali, Punjab, India, 160062  ECR/28/Inst/PB/2013/RR-24	Dr. Kiran Pal Singh
2.	SR Kalla Memorial Gastro & General Hospital, 78-79 Dhuleshwar Garden C - Scheme Jaipur Rajasthan-30206, Research Department 1st Floor, Jaipur, Rajasthan, India, 302006	S.R.Kalla Memorial Ethical Committee for Human Research 78-79, 78-79 Dhuleshwar Garden, Behind HSBC Bank, Sardar Patel Marg, C-Scheme, Jaipur, Rajasthan, India, 302001  ECR/8/INST/RAJ/2013/RR-24	Dr. Mukesh Kalla
3.	John C. Martin Centre for Liver Research & Innovations (JCMLRI), Hospital Road, Ground Floor, JCMLRI Building, IILDS Campus, Kolkata, West Bengal, India, 700150	HREC-IILDSIILDS Campus, Sitala East, Sonarpur, Kolkata, JCMLRI Building, 2nd Floor, Kolkata, West Bengal, India, 700150  ECR/1568/Inst/WB/2021	Dr. Abhijit Chowdhury
4.	Postgraduate Institute of Medical Education & Research, Sector 12, Nehru Extension Block (NHEB), Ground Floor Room no 30, Chandigarh, Chandigarh, India, 160012	Institutional Ethics Committee Room no 6006, P.N Chutani Block, 6th Floor, PGIMER, Chandigarh, Chandigarh, India, 160012  ECR/25/Inst/CH/2013/RR-25	Dr. Ajay Duseja

5.	All India Institute of Medical Sciences – Rishikesh, Virbhadra Road, Near Barrage, Uttarakhand, India, 249203	Institutional Ethics Committee, AIIMS Rishikesh Virbhadra Road, Rishikesh, Uttarakhand, India, 249203  ECR/736/Inst/UK/2015/RR-21	Dr. Rohit Gupta
6.	Lisie Hospital, Lisie Hospital Road, MON-FRI 10:00 M - 04:00 PM, Kochi, Kerala, India, 682018	Institutional review board Lisie Hospital, P B NO 3053, kloor, Kochi, Kerala, India, 682018  ECR/40/Inst/KL/2013/RR-25	Dr. Mathew Philip
7.	All India Institute of Medical Sciences, Ansari Nagar, Room No. 127, first floor HNU, Old OT block, Ansari Nagar, New Delhi, Delhi, India, 110029	Institute of Ethics Committee Room no 102, First Floor HNU OLD OT Block, New Delhi, Delhi, India, 110029  EC/RENEW/INST/2025/19419	Dr. Shalimar Sushil Kumar
8.	Dayanand Medical College and Hospital, DMC Road, Tagore Nagar, Ludhiana, Punjab, India, 141001	Drug Trial Ethics Committee Tagore Nagar, Civil Lines, Ludhiana, Punjab, India, 141001  ECR/101/INST/PB/2013/RR-24	Dr. Vandana Midha
9.	MIDAS MULTISPECIALITY HOSPITAL PVT.LTD. 392, Wardha Road, Midas Multispecialty Hospital Pvt. Ltd, Opp Singh Saab Dhaba, Parsodi, Nagpur, Maharashtra, India, 440010	Institutional Ethics Committee, Midas Multispeciality Hospital Pvt Ltd Parsodi, Wardha Road, Nagpur, Midas Heights, Mon-Fri; 11-6pm, Nagpur, Maharashtra, India, 441108  ECR/1392/Inst/MH/2014/RR-25	Dr. Shrikant Mukewar
10.	Topiwala National Medical College & B. Y. L. Nair Charitable Hospital, Dr. A. L. Nair Road, OPD Building/7th Floor/714 and 715, Mumbai central, Mumbai, Maharashtra, India, 400008	Institutional Ethics Committee Dr. A. L. Nair Road, 400 008, College building, 4th floor, R.No.419., Mumbai, Maharashtra, India, 400 008  ECR/22/Inst/Maha/2013/RR-24	Dr. Shubham Jain
11.	Mysore Medical College, K R S Road, Princess Krishnammanni Super Specialty Hospital, Third Floor, Mysore, Karnataka, India, 570001	Institutional Ethics Committee- Mysore Medical College and Research Institute and Associated Hospitals Mysore Medical College and Research Institute, Irwin Road, Mysuru-570001, Karnataka, India  ECR/134/Inst/KA/2013/RR-24	Dr. Dharmendra B L

12.	Asian Institute of Gastroenterology, Mind Space Road, Room No 7, Gachibowli, Hyderabad, Hyderabad, Telangana, India, 500032	Institutional Ethics Committee Asian Institute of Gastroenterology 6-3-661 Somajiguda, Hyderabad-500082, India, Hyderabad, Telangana, India, 500082  ECR/346/Inst/AP/2013/RR-22	Dr. Anand V Kulkarni
13.	Amrita Institute of Medical Sciences and Research Center, A Block, Tower 1, 2nd Floor, AIMS-Ponekkara, Ernakulam, Kerala, India, 682041	Institutional Ethics Committee, Amrita Institute of Medical Sciences AIMS-Ponekkara.P.O., Kochi, Edappally, Kochi, Kerala, India, 682041  ECR/129/Inst/KL/2013/RR-24	Dr. Arun Valsan
14.	All India Institute of Medical Sciences (AIIMS) – Nagpur, Plot 2 Sector 20 Mihan, Nagpur, Maharashtra, India, 441108	Ethics Committee relating to Clinical Trial MIHAN, Nagpur, Nagpur Division, Nagpur, Maharashtra, India, 440018  ECR/1392/Inst/MH/2020/RR-25	Dr. Rutwik Loya
15.	Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India, 442004	Institutional Ethics Committee of DMIHER Datta Meghe Institute of Higher, Administrative Block, University Office, Wardha, Maharashtra, India, 442107  ECR/440/Inst/MH/2013/RR-24	Dr. Vijendra Kirnake
16.	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, New Building, I Block, Lucknow, Uttar Pradesh, India, 226014	Institutional Ethics Committee SGPGIMS, Room no. 205, ADM Block, Lucknow, Uttar Pradesh, India, 226014  ECR/16/Inst/UP/2013/RR-25	Dr. Amit Goel
17.	Surat Institute of Digestive Sciences Hospitals, A unit of SIDS health care private limited, Off ring road, Near shell petrol pump, Ring road-sosyo circle lane, SURAT, Gujarat, India, 395002	Surat Institute of Digestive Sciences Ethics Committee, SIDS Hospital and Research Centre, A unit of SIDS Healthcare Private Limited., Off Ring Road, Near Shell petrol Pump, Ring Road –Sosyo circle lane, SURAT, Gujarat, India, 395002  ECR/813/Inst/GJ/2016/RR-24	Dr. Rajiv M Mehta
18.	Avron Hospitals, 4, Shantiniketan Park, Nr. Sardar Patel Statue, Naranpura, Ahmedabad, Gujarat, India, 380013	Avron Multi Speciality Hospitals Ethics Committee 4, Shantiniketan Park, Nr. Sardar Patel statue, Naranpura, beside Anjali Emporium, Ahmedabad, Gujarat, India, 380013	Dr. Tanmay Vyas

		ECR/1136/Inst/GJ/2018/RR-22	
19.	Sir Ganga Ram Hospital, Rajinder Nagar, New Delhi, Delhi, India, 110060	Ethics Committee Sir Ganga Ram Hospital Rajendra Nagar, 1643, 6th Floor, Causality Building, New Delhi, New Delhi, Delhi, India, 110060  ECR/20/Inst/DL/2013/RR-24	Dr. Ashish Kumar

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