



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/23/000053

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/2023/37599 (GCT/53/23) dated 15/05/2023, please find enclosed herewith the permission in Form CT-06 for conduct of phase 3 clinical trial titled, **"A Master Protocol to Investigate the Efficacy and Safety of LY3437943 Once Weekly in Participants without Type 2 Diabetes who have Obesity or Overweight: A Randomized, Double-Blind, Placebo-Controlled Trial (TRIUMPH-1)", Protocol No.: J11-MC-GZBJ(b) dated 21-Apr-2023 with a total of up-to 150 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) 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 Licensing Authority under rule 8;
- (ii) 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;
- (iii) 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;
- (iv) the Central Licensing 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;

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

- (xviii) 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;
- (xix) 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
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority
Stamp

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI,
2.5.4.20=80c6276a23e4e1fb8a239774cdeb03c2769
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postalCode=600034, st=TAMIL NADU,
serialNumber=657F5E47D940985D8F03BDC902D0E
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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., Sector 32, Plot No. 92, Gurgaon, Gurgaon (India) – 122001** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: J1I-MC-GZBJ(b) dated 21-Apr-2023** 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
RAJ. Rajeev Singh (Rajghwanshi)
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	LY3437943
Therapeutic class:	Antidiabetic
Dosage form:	Solution for injection
Composition:	<p>LY3437943 = 2.0000 mg/ml In House Specification Active Tris(hydroxymethyl)aminomethane =1.2100 mg/ml U.S.P. Inactive Mannitol = 48.0000 mg/ml U.S.P. Inactive</p> <p>LY3437943 = 4.0000 mg/ml In House Specification Active Tris(hydroxymethyl)aminomethane =1.2100 mg/ml U.S.P. Inactive Mannitol = 48.0000 mg/ml U.S.P. Inactive</p>

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	<p>LY3437943 = 6.0000 mg/ml In House Specification Active Tris(hydroxymethyl) aminomethane = 1.2100 mg/ml U.S.P. Inactive Mannitol = 48.0000 mg/ml U.S.P. Inactive</p> <p>LY3437943 = 9.0000 mg/ml In House Specification Active Tris(hydroxymethyl)aminomethane = 1.2100 mg/ml U.S.P. Inactive Mannitol = 48.0000 mg/ml U.S.P. Inactive</p> <p>LY3437943 = 12.0000 mg/ml In House Specification Active Tris(hydroxymethyl)aminomethane = 1.2100 mg/ml U.S.P. Inactive Mannitol = 48.0000 mg/ml U.S.P. Inactive</p>
Indications:	Type 2 Diabetes who have Obesity or Overweight

Annexure:

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Jothydev's Diabetes Research Centre, JDC Junction, Konkalam Road, Mudavanmugal, Poojappura, Trivndrum-695032	<p>Institutional Ethics Committee Jothydev's Diabetes Research Centre, JDC Junction, Konkalam Road, Mudavanmugal, Poojappura, Trivndrum-695032</p> <p>ECR/1167/Inst/KL/2019/RR-22</p>	Dr. Jothydev Kesavadev
Avron Hospitals Pvt. Ltd., 4, Shantiniketan Park, Nr. San;lar Patel Statue, Naranpura, Ahmedabad-380013	<p>Avron Multi-Speciality Hospitals Ethics Committee, 4, Shantiniketan Park, Nr. Sardar Patel Statue, Naranpura, Ahmedabad-380013</p> <p>ECR/1136/Inst/GJ/2018/RR-22</p>	Dr. Tiven Marwah
Eternal Hospital, Unit of Eternal Heart Care Centre & Research Institute Pvt. Ltd., 3A, Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan, India	<p>Eternal Heart Care Centre & Research Centre Institutional Ethics Committee, 3A, Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan, India</p> <p>ECR/615/Inst/RJ/2014/RR-20</p>	Dr. Sailesh Lodha
All India Institute of Medical Sciences, Bhubaneswar, Sijua Patrapada, Bhubaneswar-751019, Odisha	<p>Institutional Ethics Committee, All India Institute of Medical Sciences, Bhubaneswar, Sijua, P/O Patrapada, Khordha, Odisha-751019, India</p> <p>ECR/280/Inst/Maha/2013/RR-19</p>	Dr. Kishore Kumar Behra

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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 ECR/751/Inst/MH/2015/RR-21	Dr. Dange Amol Laxmanrao
Endolife Specialty Hospitals Pvt. Ltd., D. No: 12-12-94, Old Club Road, Kothapet, Guntur-522001, Andhra Pradesh, India	Institutional Ethics Committee of Endolife Hospitals Pvt. Ltd., D. No: 12-12-94, Old Club Road, Kothapet, Guntur-522001, Andhra Pradesh, India ECR/647/Inst/AP/2014/RR-17	Dr. Kongara Srikanth
Karnataka Institute of Medical Sciences, Hubli-580022	Institutional Ethics Committee, Dr. Raveendra Marg, Member Secretary, Karnataka Institute of Medical Sciences, Hubli-580022 ECR/486/Inst/KA/2013/RR-20	Dr. Ram S. Kaulgud
Wockhardt Hospitals, Mumbai Central, Police Station, 1877, Dr Anandrao Nair Marg, Near Agripada, Mumbai Central, Mumbai, Maharashtra-400011	Wockhardt Hospitals Institutional Review Board, Wockhardt Hospitals Ltd., Adams Wylie Memorial, 1877, Dr Anandrao Nair Marg, Near Agripada, Mumbai Central, Mumbai, Maharashtra-400011 ECR/624/Inst/MH/2014/RR-20	Dr. Ramen Goel
Government Medical College and Hospital, Medical College Square Road, Nagpur-440003, Maharashtra, India	Institutional Ethics Committee, Department of Pharmacology, Government Medical College and Hospital, Medical College Square Road, Nagpur-440009, Maharashtra, India ECR/43/Inst/MH/2013/RR-22	Dr. Rajesh Vithal Gosavi
Surat Institute of Digestive Sciences, A unit of SIDS Healthcare Pvt. Ltd., Vijay Nagar, Gate No. 3, Beside Nirman Bhavan, Opposite Gandhi College, Majura Gate, Ring Road, Surat-395002, Gujarat, India	Surat Institute of Digestive Sciences Ethics Committee, Surat Institute of Digestive Sciences, A unit of SIDS Healthcare Pvt. Ltd., J J Empire & Tapi Villa Building, Vijay Nagar, Gate No. 3, Beside Nirman Bhavan, Opposite Gandhi College, Majura Gate, Ring Road, Surat-395002, Gujarat, India ECR/813/Inst/GJ/2013/RR-20	Dr. Vikram Rajnikant Lotwala

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ILS Hospital, Saltlake, DD-6 Sector1, Salt lake City, Kolkata-700064	ILS Hospital Ethics Committee, DD-6 Sector1, Salt lake City, Kolkata-700064 ECR/130/Inst/WB/2013/RR-19	Dr. Ghanshyam Goyal
Post Graduation Institute of Medical Education & Research (PGIMER), Department of Endocrinology, Room No. 9, Ground Floor, Nehru Extension, PGIMER, Chandigarh-160012	Institutional Ethics Committee, P. N. Chuttani Block, Room No. 6006, 6 th Floor, Research Block, PGIMER, Chandigarh-160012 ECR/25/Inst/CH/2013/RR-20	Dr. Rama Walia
Christian Medical College, 810, Dept. of Endocrinology Diabetes & Metabolism, Christian Medical College, Vellore-4, India, T.N.	Institutional Review Board, Carman Block, Christian Medical College, Bagayam, Vellore-632002, Tamil Nadu, India ECR/326/Inst/TN/2013/RR-19	Dr. Nitin Kapoor
Deenanath Mangeshkar Hospital & Research Center, Erandwane Pune-411004	Institutional Ethics Committee of Deenanath Mangeshkar Hospital, 14 th Floor, Deenanath Mangeshkar Hospital & Research Center, Erandwane Pune-411004 ECR/15/Inst/Maha/2013/RR-19	Dr. Vaishali Chetan Deshmukh
Grant Government Medical College and Sir JJ Group of Hospitals, Byculla, Mumbai-400008, Maharashtra, India	Institutional Ethics Committee, New healthcare Nursing Home, C Satellite Park, Near GCC Club Mira Road (East), Thane, Maharashtra-401107 ECR/388/Inst/MH/2020	Dr. Gupta Hemant Ramsharan
Chellaram Diabetes Institute, 1 st Floor, Lalani Quantum, Pune- Bangalore National Highway-4, Bavdhan (Budruk), Pune-411021, Maharashtra, India	Chellaram Diabetes Institute- Institutional Ethics Committee, Chellaram Diabetes Institute, Lalani Quantum, Pune- Bangalore National Highway-4, Bavdhan (Budruk), Pune-411021, Maharashtra, India ECR/203/Inst/MH/2014/RR-20	Dr. Unnikrishnan A G
Indian Institute of Diabetes, Pulayanarkotta, Thiruvananthapuram-695031, Kerala, India	Institutional Ethics Committee, Indian Institute of Diabetes, Pulayanarkotta, Thiruvananthapuram-695031, Kerala, India ECR/688/Inst/KL/2014/RR-20	Dr. P K Jabbar
