File No. CT/92/19-DCG(I)

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

सत्यमेव जयते

File No. CT/19/000095

To,

M/s. Eli Lilly and Company (India) Pvt. Ltd.,
Plot No. 92, Gurgaon, Sector 32,
Gurgaon – 122001, Haryana.

Sir,

With reference to your application No GCT/CT04/FF/2019/17389 (GCT92/19) dated 29-11-2019, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, "**Efficacy and Safety of Tirzepatide Once Weekly in Participants without Type 2 Diabetes Who Have Obesity or are Overweight with Weight-Related Comorbidities: A Randomized, Double-Blind, Placebo-Controlled Trial (SURMOUNT-1)", Protocol number I8F- MC-GPHK dated 09/Sep/2019** 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 Licencing 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 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;

(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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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) 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,

V G SOMANI

Digitally signed by V G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, 2.5.4.20=111d9c06dbcb941e6f5d9fed4cea2e8 4142a223ncae4ab1512cbee652020f9f, ou=DGHS,CID - 6445798, postalCode=110002, st=Delhi, cn=V G SOMANI
Date: 2020.02.18 17:30:14 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing Authority
Stamp

File No. CT/92/19-DCG(I)

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, (India) – 122001** to conduct clinical trial of the new drug or investigational new drug as per protocol number **I8F-MC-GPHK dated 09/Sep/2019** 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 _____

V G SOMANI

Digitally signed by V G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, 2.5.4.20=111d9c06dbc3941ef5d9fed4ccaa2e84142a222ecae4ab15112cbee65202ff8f, ou=DGHS,CID - 6445798, postalCode=110002, st=Delhi, cn=V G SOMANI
Date: 2020.02.18 17:30:23 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing 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	Tirzepatide
Therapeutic class:	Incretin Injection
Dosage form:	Solution for Injection

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Composition:	Water for injection=0.5000 ml U.S.P. Inactive Sodium Chloride =4.1000 milligram (mg) U.S.P, Inactive Sodium phosphate dibasic heptahydrate =0.6700 milligram (mg) U.S.P. inactive LY3298176 =2.5000 milligram (mg) in House Specification Active Water for injection=0.5000 ml U.S.P. Inactive Sodium Chloride =4.1000 milligram (mg) U.S.P, Inactive Sodium phosphate dibasic heptahydrate =0.6700 milligram (mg) U.S.P. inactive LY3298176 =5.0000 milligram (mg) in House Specification Active Water for injection=0.5000 ml U.S.P. Inactive Sodium Chloride =4.1000 milligram (mg) U.S.P, Inactive Sodium phosphate dibasic heptahydrate =0.6700 milligram (mg) U.S.P. inactive LY3298176 =7.5000 milligram (mg) in House Specification Active Water for injection=0.5000 ml U.S.P. Inactive Sodium Chloride =4.1000 milligram (mg) U.S.P, Inactive Sodium phosphate dibasic heptahydrate =0.6700 milligram (mg) U.S.P. inactive LY3298176 =10.0000 milligram (mg) in House Specification Active Water for injection=0.5000 ml U.S.P. Inactive Sodium Chloride =4.1000 milligram (mg) U.S.P, Inactive Sodium phosphate dibasic heptahydrate =0.6700 milligram (mg) U.S.P. inactive LY3298176 =12.5000 milligram (mg) in House Specification Active Water for injection=0.5000 ml U.S.P. Inactive Sodium Chloride =4.1000 milligram (mg) U.S.P, Inactive Sodium phosphate dibasic heptahydrate =0.6700 milligram (mg) U.S.P. inactive LY3298176 =15.0000 milligram (mg) in House Specification Active
Indications:	Participants without Type 2 Diabetes who have Obesity or are Overweight with Weight-Related Comorbidities

Details of clinical trial site:

Names and address of clinical trial site	**Ethics committee details**	**Name of investigator**
Fortis Hospital, AA Block, Shalimar Bagh, New Delhi-110088	Institutional Ethics Committee, Fortis Hospital, AA Block, Shalimar Bagh, New Delhi-110088 ECR/513/Inst/DL/2014/RR-17	Dr. Ajay Aggarwal
CARE Out Patient Centre D No # 8-2-620/A-E, Road No 10 Banjara Hills, Hyderabad, 500034	Institutional Ethics Committee, D No # 8-2-595/2/B, Care Convergence Centre, Road No 10, Baniara Hills Hyderabad, 500034 ECR/94/Inst/AP/2013/RR-19	Dr Bipin Kumar Sethi

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ILS Hospital Salt Lake, DD-6.Sector 1, Salt Lake City, Kolkata-700064	ILS Hospital Ethics Committee, DD-6.Sector 1, Salt Lake City, Kolkata-700064 ECR/130/Inst/WB/2013/RR-19	Dr. Ghanshyam Goyal
Amrita Institute of Medical Sciences and Research Centre AIMS-Ponekkara. P.O, Kochi-682041, Kerala, India	Institutional Ethics Committee, Amrita Institute of Medical Sciences and Research Centre, AIMS-Ponekkara. P.O, Kochi-682041, Kerala, India ECR/129/Int/KL/2013/RR-19	Dr. Harish Kumar
Grant Government Medical College and sir J J Group of Hospitals Grant Government Medical College and sir J J Group of Hospitals, Byculla, Mumbai -400008	Institutional Ethics Committee, GGMC Mumbai, Grant Govt. Medical College JJ ROAD, JJ Hospital compound Mumbai central Mumbai city Maharashtra -400008 India ECR/382/Inst/MH/2013/RR-19	Dr. Gupta Hemant Ramsharan
Department of Endocrinology, 4th Floor, R. No. 419, College Building, Dr. A. L. Nair Road, TNMC and BYL Nair CH. Hospital Mumbai-400 008	Institutional Ethics Committee, 'G' building, Ground Floor, TNMC and BYL Nair CH. Hospital, Mumbai-400 008 ECR/22/Inst/Maha/2013/RR-19	Dr. Jugal Velji Gada
All India Institute of Medical Sciences, AIIMS, New Delhi, 110029	Institute Ethics Committee AIIMS, 102,First Floor, Old OT Block, AIIMS, Ansari Nagar, New Delhi-110029 ECR/547/Inst/DL/2014/RR-17	Dr. Naval K. Vikram
Gujarat Endocrine Centre, 2nd Floor, Silver Brook-B, Opp Doctor House, Nr Parimal Crossing, Ellis Bridge, Ahmedabad-380006	Gastro Plus Ethics Committee, D Block, 3rd Floor, Galaxy bazaar, Sunrise Park-Road, Vastrapur, Ahmedabad-380054 ECR/1207/Inst/GJ/2019	Dr. Shah Parag Rajnikant
CHL Hospitals [Unit of Convenient Hospitals Ltd.,] Near L. l. G Square, A B Road, Indore, Madhya Pradesh, India - 452008	Integrity Ethics Committee, Convenient Hospitals Ltd , CHL – Hospitals Near L. l. G. Square, A. B. Road, Indore, Madhya Pradesh, lndia – 452008 ECR/505/Inst/MP/2014/RR-17	Dr. Sandeep Julka
Department Of Endocrinology, Deenanath Mangeshkar Hospital and Research Center , SS Building Endocrinology Department, Research Room, Erandwane Pune-411004	Institutional Ethics committee, Department of Research , 14th Floor C wing, Super Specialty Building , Deenanath Mangeshkar Hospital and Research Center off Karve Road Erandwane Pune - 411004 Maharashtra, India ECR/15/Inst/Maha/2013/RR-19	Dr. Vaishali Deshmukh