

F. No. BIO/CT/19/000070  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

From,

The Drugs Controller General, India  
Directorate General of Health Services,

FDA Bhawan Kotla Road,  
New Delhi-110002

To,

M/s Eli Lilly and Company (India) Pvt. Ltd,  
Plot no. 92, Institutional area,  
Sector 32 Gurgaon-122001, Haryana, India

Subject: Application for conduct of Phase IV clinical study titled "A Multicenter, Open-Label, Single-Arm, Phase 4 Study to Assess the Safety of Basaglar in Subjects with Type 2 Diabetes Mellitus in India" vide Protocol I4L-IN-ABEX(b), dated 04-Oct-2019 – regarding

Sir,

With reference to your Application No.: BIO/CT04/FF/2019/15886, dated 31-Jul-2019, please find enclosed herewith the permission in FORM CT-06 for conduct of subject mentioned Phase IV clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter 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 Licensing 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 Licensing 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 Licensing 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 Licensing 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing 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 Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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) 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;
- (xv) The Central Licensing 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;
- (xvi) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

Yours faithfully

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

**FORM CT-06**

*(See rules 22, 25, 26, 29 and 30)*

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR  
INVESTIGATIONAL NEW DRUG**

The Central Licensing Authority hereby permits **M/s Eli Lilly and Company (India) Pvt. Ltd, Plot no. 92, Institutional area, Sector 32 Gurgaon-122001, Haryana, India** to conduct clinical trial of the new drug as per Protocol I4L-IN-ABEX(b), dated 04-Oct-2019 in the below mentioned clinical trial sites [as per Annexure].

2. Details of 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. V. G. Somani)  
Drugs Controller General (India)  
Central Licensing Authority

**Annexure:****Details of New Drug or Investigational New Drug:**

Names of the new drug or investigational new drug:	Insulin Glargine I.P.		
Therapeutic class:	Anti diabetic		
Dosage form:	Solution for Injection (SC)		
Composition:	Ingredient	Quantity/mL	Function
	Insulin Glargine	100 Units	Active
	Glycerine	17.0 mg	Tonicity modifier
	Metacresol	2.7 mg	Preservative
	Zinc Oxide	q.s. to provide Zn <sup>2+</sup> content of 0.03 mg	Stabilizer
	HCl Acid Sol. 10%	q.s. to adjust the pH	pH adjustment
	NaOH Sol. 10%	q.s. to adjust the pH	pH adjustment
	Water for Injection	q.s. to 1 mL	Vehicle
Indications:	Type 2 Diabetes		

**Details of clinical trial sites:**

S. No.	Names and Address of Clinical Trial Site	Ethics Committee Details	Name Of Principal Investigator
1	Sir Ganga Ram Hospital SGRH Marg, Rajinder Nagar, New Delhi – 110060	Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital Room No. 1496. IV Floor, Old Building Old Rajinder nagar at New Delhi – 110060 EC Reg. No: ECR/20/Inst/DL/2013/RR-2019	Dr. Surender Kumar
2	Supe Heart & Diabetes hospital & Research Centre, Opp. Adharashram, Gharpure Ghat, Near Rungtha School, Ashok Stambha, Nashik, Maharashtra – 422002, India	Supe Hospital Ethics Committee, Supe Heart Diabetes Hospital and Research Centre, Opp. Adharashram, Gharpure Ghat, Near Rungtha School, Ashok Stambha, Nashik, Maharashtra – 422002, India EC Reg. No: ECR/272/Inst./MH/2013/RR-2019	Dr. Preetam Ahirrao
3	Maharaja Agrasen Hospital, West Punjabi Bagh, New Delhi - 110026	Institutional Ethics Committee, Maharaja Agrasen Hospital, R.No.- 614, 6 <sup>th</sup> Floor, West Punjabi Bagh, New Delhi-110026 EC Reg. No: ECR/745/Inst/DL/2015/RR-18	Dr. Deepak Khandelwal
4	Bangalore Diabetes Centre No. 426, 4th cross, 2nd block, Kalyan Nagar, Bangalore - 560043, Karnataka	Medisys Clinisearch Ethical Review Board Bangalore Diabetes Center, No 426, 2nd Cross, 2nd Block, Kalyan Nagar, Bangalore - 560043, Urban Karnataka EC Reg. No: ECR/33/Inst/KA/2013/RR-19	Dr. Paramesh Shamanna

5	Gujarat Endocrine Centre, 201-B, Silver Brook Bldg, Opp Doctor House, Nr Parimal Crossing, Ahmedabad - 380006, Gujarat	Gastro Plus Ethics Committee situated at Gastro Plus Hospital, D-Block, 3 <sup>rd</sup> Floor, Galaxy Bazaar, Sunrise Park Road, Vastrapur, Ahmedabad - 380006, Gujarat EC Reg. No: ECR/1207/Inst/GJ/2019	Dr. Parag Shah
6	Indraprastha Apollo Hospitals, Endocrinology (Diabetes Care) Indraprastha Apollo Hospitals, Delhi Mathura Road, New Delhi - 110076	Institutional Ethics Committee – Clinical studies at Indraprastha Apollo Hospitals, Sarita Vihar, New Delhi EC Reg. No: ECR/5/Inst/DL/2013/RR-16	Dr. Chandra Mohan Batra
7	Nirmal Hospital Pvt. Ltd., Ring Road, Surat, Surat – 395002, Gujarat	Nirmal Hospital Ethics Committee, Nirmal Hospital Pvt. Ltd., 2/1423-8-6 Sagrampura Ring Road, Near Centre Point, Surat - 395002, Gujarat EC Reg. No: ECR/390/Inst/GJ/2013/RR-19	Dr. Piyush Desai
8	Popular Hospital, Popular Hospital N10/60 A-2 DLW Road, Kakarmatta, Varanasi – 221004, UP	Popular Hospital Ethics Committee, N-10/60, A-2, D. L. W. Road, Kakarmatta, Varanasi Uttar Pradesh - 221009 EC Reg. No: ECR/721/Inst/UP/2015/RR-18	Dr. Indraneel Basu
9	Diacare Research, 1-2, Gandhi Park, Near Nehrunagar Road, Ambawadi, Ahmedabad-380015, Gujarat	Gastro Plus Ethics Committee situated at Gastro Plus Hospital, D-Block, 3 <sup>rd</sup> Floor, Galaxy Bazaar, Sunrise Park Road, Vastrapur, Ahmedabad - 380006, Gujarat EC Reg. No: ECR/1207/Inst/GJ/2019	Dr. Banshi Saboo
10	Dhiraj Hospital, Sumandeep Vidyapeeth At & Po. Pipariya, Tal-Waghodia, Dist – Vadodara - 391760, Gujarat	Institutional Ethics Committee, Dhiraj Hospital, Sumandeep Vidyapeeth AT & PO Pipariya, Vadodara, Gujarat - 391760 EC Reg. No: ECR/152/INST/GJ/2013/ RR-19	Dr. Hetal Pandya
11	Department of Medicine, Sir Sayajirao General Hospital, Jail road (Indira Avenue), Vadodara - 390001, Gujarat	Human Research Medical College and SSG Hospital at Department of Pharmacology, 1st Floor, Anandpura, Vadodara-390001, Gujarat, India EC Reg. No: ECR/85/Inst/GJ/2013/RR-16	Dr. Keyur Brahme
12	Ganesh Shankar Vidyarthi Memorial Medical College, Swaroop Nagar, 208002, Kanpur, UP	Ethics Committee, GSVM Medical College at Room No-125, 1 <sup>st</sup> Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh India EC Reg. No: ECR/680/Inst/UP/2014/RR-17	Dr. Saurabh Agarwal