

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

1. The Central Licensing Authority hereby permits **M/s IQVIA RDS (India) Pvt. Ltd., 2nd Floor, Etamin Block, Prestige Tech Park II, Marathahalli- Sarjapur Outer Ring Road, Bangalore-560103** to conduct clinical trial of the new drug or investigational new drug as per protocol number **LPS15396 version number 1 dated 17/07/2018** 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 ct, 1940.

Place: New Delhi

Date _____

(Dr. S. Eswara Reddy)
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	Toujeo 300 units/ml solution for injection in pre-filled pen [Insulin Glargine (Gla-300)]
Therapeutic class:	Antidiabetic
Dosage form:	Gla-300(Toujeo) will be supplied as a sterile, non pyrogenic, clear, colorless solution in SoloStar® prefilled (disposable) pen for SC injection
Composition:	Insulin Glargine (Gla-300)
Indications	Type 2 Diabetes Mellitus uncontrolled on basal Insulin

File No. CT/26/19-DCG(I)

Details of clinical trial site:

Names and address of clinical trial site	Ethics committee details	Name of investigator
Fortis Hospital, Sector-62, Phase-VIII, Mohali Punjab-160062, India	Institutional Ethics Committee, Fortis Hospital, Sector-62, Phase-VIII, Mohali Punjab-160062, India ECR/28/Inst/PB/2013/RR-16	Dr. Kiran Pal Singh
CIMET"s Inamdar Multispeciality Hospital, Fatima Nagar, Pune 411040, Maharashtra	Institutional Ethics committee, Inamdar Multispeciality Hospital, Hospital Building, Sr. No. 15, Fatima Nagar, Pune 411040, Maharashtra ECR/354/Inst/MH/2013/RR-16	Dr. Kadam Yogesh Dashrath
Kovai Diabetes Speciality Centre and Hospital, No. 15, Vivekananda Road, Ram Nagar, Coimbatore-641009, Tamil Nadu	Institutional Ethics Committee of Kovai Diabetes Speciality Centre and Hospital, No. 15, Vivekananda Road, Ram Nagar, Coimbatore-641009, Tamil Nadu ECR/233/Inst/TN/2013/RR-16	Dr. Balamurugan Ramanathan
Care Hospital, Care Out Patient Centre#8-2-620/A-E S, Road No. 10, Banjara Hills, Hyderabad, 500034	Institutional Ethics Committee, (IEC), Care Foundation Road No. 10, Banjara Hills, Hyderabad, 500034 ECR/94/Inst/AP/2013/RR/16	Dr. Bipin Kumar Sethi
All India Institute of Medical Sciences (AIIMS), Room No. 8, Cross wing, SRB Centre, 3 rd Floor, Teaching Block, AIIMS, New Delhi-110029, India	Institutional Ethics Committee, All India Institute of Medical Sciences Ansari Nagar, New Delhi-110029, India ECR/538/Inst/DL/2014/RR-17	Dr. Naval K Vikram
M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India	Institutional Ethics Committee, M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore-560054, Karnataka, India ECR/215/Inst/KA/2013/RR-16	Dr. Pramila Kalra
King George's Medical University, Department of Endocrinology, Shatabdi Phase-2, 6 th floor, Chowk-226003 Lucknow Uttar Pradesh, India	Institutional Ethics Committee Administrative Block, Office of Research Cell, King George's Medical University, Chowk-226003 Lucknow Uttar Pradesh, India ECR/262/Inst/UP/2013/RR-16	Dr. Madhukar Mittal
IPGMER & SSKM Hospital 244, A.J.C.	IPGME&R, RESEARCH OVERSIGHT COMMITTEE, Institute of Post	Dr. Gouranga Sarkar

File No. CT/26/19-DCG(I)

Bose Road, Kolkata, West Bengal 700020, India	Graduate Medical Education & Research Oversight Committee, Office of the Dean, College Building 5 th Floor, 244, A.J.C. Bose Road, Kolkata, West Bengal 700020, India ECR/35/Inst/WB/2013/RR-16	
---	---	--