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
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

File No. CT/25/000106

To,

M/s Sun Pharmaceutical Industries Limited,
Tandalja, Vadodara, Gujarat (India) – 390012.

Sir,

With reference to your application No. GCT/CT04/FF/2025/51036 dated 25-Jul-2025, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **"A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Tolerability of GL0034 Among Type II Diabetes Mellitus Subjects who are Obese or Overweight With Weight-related Comorbidities" Protocol No.: UTRE-24-01 Version no. initial dated 12 June 2025 with a total of up-to 120 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 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) 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
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.29 11:50:06 +05'30'

(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 Sun Pharmaceutical Industries Limited, Tandalja, Vadodara Vadodara (India) - 390012** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: UTRE-24-01 Version no. initial dated 12 June 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 _____

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.29 11:50:16 +05'30'

(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:

Names of the new drug or investigational new drug	Utreglutide (GL0034) Solution for injection 0.75 mg/mL, 1.0mg/mL, 1.5 mg/ml 3mg/mL, 4.5 mg/mL, 6.0 mg/mL
	Utreglutide (GL0034) Solution for injection 0.75 mg/mL, 1.0mg/mL, 1.5 mg/ml 3mg/mL, 4.5 mg/mL, 6.0 mg/mL

	Utreglutide (GL0034) Solution for injection 0.75 mg/mL, 1.0mg/mL, 1.5 mg/ml 3mg/mL, 4.5 mg/mL, 6.0 mg/mL
	Utreglutide (GL0034) Solution for injection 0.75 mg/mL, 1.0mg/mL, 1.5 mg/ml 3mg/mL, 4.5 mg/mL, 6.0 mg/mL
	Utreglutide (GL0034) Solution for injection 0.75 mg/mL, 1.0mg/mL, 1.5 mg/ml 3mg/mL, 4.5 mg/mL, 6.0 mg/mL
	Utreglutide (GL0034) Solution for injection 0.75 mg/mL, 1.0mg/mL, 1.5 mg/ml 3mg/mL, 4.5 mg/mL, 6.0 mg/mL
Therapeutic class:	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
	Antidiabetic
Dosage form:	Solution for injection
	Solution for injection
	Solution for injection
	Solution for injection
	Solution for injection
	Solution for injection
Composition:	Utreglutide (GL0034) =0.7500mg/ml In House Specification Active
	Utreglutide (GL0034) =1.0000mg/ml In House Specification Active
	Utreglutide (GL0034) =1.5000mg/ml In House Specification Active
	Utreglutide (GL0034) =3.0000mg/ml In House Specification Active
	Utreglutide (GL0034) =4.5000mg/ml In House Specification Active
	Utreglutide (GL0034) =6.0000mg/ml In House Specification Active
Indications:	For the treatment of type II diabetes mellitus
	For the treatment of type II diabetes mellitus
	For the treatment of type II diabetes mellitus
	For the treatment of type II diabetes mellitus
	For the treatment of type II diabetes mellitus
	For the treatment of type II diabetes mellitus

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Topiwala National Medical College and BYL Nair Charitable Hospital, G Building Ground Floor, Dr A.L Nair Road, Mumbai Central Mumbai Central Maharashtra	Institutional Ethics Committee TNMC NAIR HOSPITAL, Topiwala National Medical College Nair Hospital Dr A L Nair Road Mumbai Central Mumbai City Maharashtra -400008 India ECR/22/Inst/Maha/2013/RR-24	Dr Nikhil Madhusudan Bhagwat

2.	Deenanath Mangeshkar Hospital and Research Centre, Department of Research, 6th Floor C Wing, Deenanath Mangeshkar Hospital and Research Centre , Off Karve Road. Erandawane Pune Maharashtra - 411004	Institutional Ethics committee, Deenanath Mangeshkar Hospital And Research Centre, Deenanath Mangeshkar Hospital And Research Centre Off Karve Road Erandawane Pune Maharashtra-411004 India ECR/15/Inst/Maha/2013/RR-22	Dr Vaishali Chetan Deshmukh
3.	Seth GS Medical College and KEM Hospital, Institutional Ethics Committee I, Seth GS Medical College and KEM Hospital, Parel, Mumbai Maharashtra - 400012	Institutional Ethics Committee-I Seth GS Medical College and KEM Hospital, Seth GS Medical College and KEM Hospital, Mumbai.Acharya Donde Marg, Parel,Mumbai 400012.India Mumbai City Maharashtra -400012 India ECR/229/Inst/MH/2013/RR-24	Dr Bandgar Tushar Ramkrishna
4.	Christian Medical College, Research Office, First Floor, Carman Block, Christian Medical College, Vellore Tamil Nadu - 632002	INSTITUTIONAL REVIEW BOARD, CHRISTIAN MEDICAL COLLEGETHORAPADI POST BAGAYAM VELLORE Vellore, Tamil Nadu -632012 India ECR/326/Inst/TN/2013/RR-24	Dr Nitin Kapoor
5.	BSES Municipal General Hospital, Office of Ethcis Committee, 2nd floor BSES MG Hospital, S.V Road, Andheri West Mumbai Maharashtra -400058	BSES Municipal General Hospital Ethics Committee, BSES MUNICIPAL GENERAL HOSPITAL. SV ROAD, OPP RAILWAY STATION ANDHERI, WEST ECR/343/Inst/MH/2013/RR-24	Dr Manoj S Chawla
6.	All India Institute of Medical Sciences, Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1stFloor, Old O.T. Block, Ansari Nagar, New Delhi Delhi -110029	Institute Ethics Committee All India Institute of Medical Sciences, Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 New Delhi South Delhi -110029 India ECR/538/Inst/DL/2014/RR-20	Dr Rajesh Khadgawat
7.	Endolife Speciality Hospitals Pvt. Ltd.,, Ethics Committee, Endolife Speciality Hospitals Pvt. Ltd., D.No: 12-12-94, Old Club Road, Kothapet Guntur Andhra Pradesh - 522001	IEC-ESH Endolife Speciality Hospitals Pvt.Ltd. 12-12-94, Old Club Road, Kothapet Old Club Road, Kothapet. Guntur Andhra Pradesh -522001 India ECR/647/Inst/AP/2014/RR-20	Dr Kongara Srikanth
8.	Life Care Hospital and Research Centre, 2748-2152, M.L.N Enclave, 16th E Cross Road, 8th Main, D-Block Next to Corportion Bank, Sahakarnagar Bangalore Karnataka - 560092	Life Care Hospital Institutional Review Board, Life Care Hospital and Research Centre, 2748/2152 M.L.N Enclave, 16th East Cross Road, 8th Main, D block, Next to Corporation Bank, Sahakarnagara, Bangalore, Karnataka, India, 560092	Dr L Sreenivasa Murthy

		ECR/883/Inst/KA/2017/RR-25	
9.	Jothydevs Diabetes Research Centre, JDC Junction Konkalam Road Mudavanmugal Kerala	Institutional Ethics Committee, JDC Junction Konkalam Road Mudavanmugal Thiruvananthapuram Kerala - 695032 India ECR/1167/Inst/KL/2019/RR-22	Dr Jothydev Kesavadev
10.	Lady Hardinge Medical College and S.S.K. Hospital, Room No.1014, Dept. of Medicine, Lady Hardinge Medical College and S.S.K. Hospital, Shaheed Bhagat Singh Marg New Delhi Delhi - 110001	LHMC Institutional Ethics Committee, Lady Hardinge Medical College and Ass Hospitals, Shaheed Bhagat Singh Marg Opposite Shivajii Stadium New Delhi New Delhi -110001 India ECR/435/Inst/DL/2013/RR-20	Dr Anupam Prakash
11.	Government Medical College, Government Medical College, Kozhikode, Mavoor road,Medical College Junction 17, Kozhikode Kozhikode Kerala -673008	Institutional Ethics Committee, Govt Medical College Kozhikode 4th Floor, Golden Jubilee Annex Institute of Maternal and Child Health Kozhikode Kerala -673008 India ECR/395/Inst/KL/2013/RR-20	Dr Aquil Kalanad
12.	Madras Diabetes Research Foundation, No. 04 Conran Smith Road, Gopalapuram Chennai Tamil Nadu - 600086	IEC of Madras Diabetes Research Foundation, Madras Diabetes Research Foundation4, ConranSmith Road Gopalapuram Chennai, Chennai Tamil Nadu - 600086 India ECR/194/Inst/TN/2013/RR-24	Dr V Mohan
13.	Poona Diabetes Centre, Unit No. 12 to 14, Ground Floor, Gulmohar Apartment, 2420, East Street, Next to SBI, Camp Pune Maharashtra - 411001	Ethics Committee Inamdar Multispeciality Hospital, CIMETs Inamdar Multispeciality Hospital. Hospital Building S. No.15, Fatima Nagar, Wanawadi. Pune Maharashtra -411040 India ECR/354/Inst/MH/2013/RR-25	Dr Kadam Yogesh Dashrath

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