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/21/000028

To

M/s. Novo Nordisk India Pvt Ltd.,
Plot No.32, 47-50, EPIP Area, Whitefield,
Bangalore, Karnataka (India) – 560066.

Sir,

With reference to your SUGAM application no. GCT/CT04/FF/2021/24350 (GCT/28/21) dated 10-MAR-2021, please find enclosed herewith the permission in Form CT-06 for conduct of Phase IIIa clinical trial titled, "**Effect of Semaglutide 2.4 mg Once-Weekly on Function and Symptoms in Subjects with Obesity Related Heart Failure with Preserved Ejection Fraction, and Type 2 Diabetes (STEP HFpEF DM Study)" Protocol Number: EX9536-4773, Version 2.0 (Amendment 1) dated 22-JAN-2021** 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:-

1) **Heart failure mortality as one of the co-secondary end point of the study.**
2) **Echocardiography should be performed for each subject twice (at the beginning and at the end), not only in a sub-group.**
3) 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;
4) 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;
5) 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;

6) 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

7) 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;

8) 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;

9) 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;

10) 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;

11) 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;

12) 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;

13) 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;

14) 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;

15) 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;

16) 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;

17) 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;

18) 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;

19) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

20) 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,

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
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Date: 2021.08.10 14:44:51 +05'30'

(Dr. V. G. Somani)
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. Novo Nordisk India Pvt. Ltd., Plot No. 32, 47-50, EPIP Area, Whitefield, Bangalore (India) - 560066** to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: EX9536-4773, Protocol Version 2.0 (Amendment 1) dated 22-JAN-2021** 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 _____

VENUGOPAL GIRDHARILAL SOMANI

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

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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	SEMAGLUTIDE
Therapeutic class:	Anti-diabetic
Dosage form:	Solution for injection
Composition:	Water for Injection = 1.0000 Volume/Volume (V/v) U.S.P., E.P.,J.P. Inactive Hydrochloric Acid = 1.0000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Hydroxide = 10000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Chloride = 8.2500 mg/ml U.S.P., E.P.,J.P. Inactive Disodium hydrogen Phosphate, Dihydrate = 1.4200 mg/ml U.S.P., E.P., Inactive Semaglutide = 1.0000 mg/ml In House Specification Active ---------- Water for Injection = 1.0000 Volume/Volume (V/v) U.S.P., E.P.,J.P. Inactive

	Hydrochloric Acid = 1.0000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Hydroxide = 10000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Chloride = 8.2500 mg/ml U.S.P., E.P.,J.P. Inactive Disodium hydrogen Phosphate, Dihydrate = 1.4200 mg/ml U.S.P., E.P., Inactive Semaglutide = 2.0000 mg/ml In House Specification Active ---------- Water for Injection = 1.0000 Volume/Volume (V/v) U.S.P., E.P.,J.P. Inactive Hydrochloric Acid = 1.0000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Hydroxide = 10000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Chloride = 8.2500 mg/ml U.S.P., E.P.,J.P. Inactive Disodium hydrogen Phosphate, Dihydrate = 1.4200 mg/ml U.S.P., E.P., Inactive Semaglutide = 2.2700 mg/ml In House Specification Active ---------- Water for Injection = 1.0000 Volume/Volume (V/v) U.S.P., E.P.,J.P. Inactive Hydrochloric Acid = 1.0000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Hydroxide = 10000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Chloride = 8.2500 mg/ml U.S.P., E.P.,J.P. Inactive Disodium hydrogen Phosphate, Dihydrate = 1.4200 mg/ml U.S.P., E.P., Inactive Semaglutide = 3.2000 mg/ml In House Specification Active ---------- Water for Injection = 1.0000 Volume/Volume (V/v) U.S.P., E.P.,J.P. Inactive Hydrochloric Acid = 1.0000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Hydroxide = 10000 q.s. U.S.P., E.P.,J.P. Inactive Sodium Chloride = 8.2500 mg/ml U.S.P., E.P.,J.P. Inactive Disodium hydrogen Phosphate, Dihydrate = 1.4200 mg/ml U.S.P., E.P., Inactive Semaglutide = 0.5000 mg/ml In House Specification Active
Indications:	Obesity related HFpEF and Type 2 Diabetes Mellitus

Annexure:

Details of clinical trial site:

S. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Department of Cardiology, Room No. 133, First Floor, Academic Block, G.B. Pant Institute of Postgraduate Medical Education & Research, Jawahar Lal Nehru Marg, New Delhi-110002	Institutional Ethics Committee, Room No. 306-A Maulana Azad Medical College, New Delhi-110002	Dr. Vimal Mehta
2.	Department of Cardiology, VMMC & Safdarjung Hospital, New Delhi-110029	Institutional Ethics Committee, VMMC & Safdarjung Hospital, Room No. 505 & 506, 5th Floor, Old Building, VMMC & Safdarjung Hospital, New Delhi-110029	Dr. Sandeep Bansal

3.	Department of Cardiology, King George's Medical University, Chowk-226003, Lucknow, U.P.	Institutional Ethics Committee, Office of the Research Cell, King George's Medical University, U.P. 226003	Dr. Rishi Sethi
4.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060	Sir Ganga Ram Hospital Ethics Committee, Room Number 1496, 4th Floor, Old Building, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060	Dr. Jitender Pal Singh Sawhney
5.	Apollo Hospitals, No. 21, Greams Lane, Off Greams Road, Chennai-600006, Tamil Nadu	Institutional Ethics Committee-Clinical Studies, Apollo Hospitals Enterprises Limited, #21, Greams Lane, Off Greams Road, Thousand Lights, Chennai-600006, Tamil Nadu	Dr. Abraham Oomman
6.	Research Cell, Department of Cardiology (HRMC), S.P. Medical College & A.G. Hospitals, Bikaner, Rajasthan-334003	Ethics Committee, S.P. Medical College, Bikaner, Rajasthan-334003	Dr. Devendra Kumar Agarwal
7.	Vijan Hospital & Research Centre (Vijan Cardiac & Critical Care Centre), Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra	Vijian Hospital Ethics Committee, Vijan Cardiac & Critical Care Centre, Dr. Vijan Hospital Marg, College Road, Nashik-422005, Maharashtra	Dr. Vinodkumar M. Vijan
8.	Max Super Specialty Hospital Saket, (East Block), (A Unit of Devki Devi Foundation) 2, Press Enclave Road, New Delhi-110017	Institutional Ethics Committee, Service Floor, Office of Ethics of Committee, East Block, Next to Conference Room, Max Super Specialty Hospital Saket, (East Block), (A Unit of Devki Devi Foundation) 2, Press Enclave Road, New Delhi-110017	Dr. Vijay Kumar Chopra

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