



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/21/000152

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 application No. GCT/CT04/FF/2021/29094 (GCT/152/21) dated 19-11-2021, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“Effects of Semaglutide on functional capacity in patients with type 2 diabetes and peripheral arterial disease (STRIDE)”**, **Protocol Number: NN9535-4533, Protocol Version 5.0 dated 15-October-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) **Echocardiography and digital X-Ray of foot should be mandatory and should be performed for all subjects during screening visit;**
- 2) **The clinical study team in each site should comprise of an Endocrinologist and an Internal medicine specialist/Cardiologist;**
- 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 Licensing 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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

File No. CT/152/21-DCG(I)

during clinical trial.

- 20) 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;
- 21) 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 G SOMANI
Dr. V. G. Somani
Drugs Controller General (India)
Central Licensing Authority
Stamp

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL, ou=ORGANIZATION OF DRUGS
CONTROLLER GENERAL (INDIA),
ou=Drugs Controller General (India),
ou=Central Licensing Authority, o=Ministry of Health and Family Welfare,
ou=Government of India, cn=VENUGOPAL G SOMANI
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ou=Ministry of Health and Family Welfare, ou=Government of India, cn=VENUGOPAL G SOMANI
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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: NN9535-4533, Protocol Version 5.0 dated 15-October-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 G SOMANI
Drugs Controller General (India)
Central Licensing Authority Stamp

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER GENERAL (INDIA),
pseudoym=112046a34e21727baca22574
8731c456d249073e55e953d9cb5b58748ee
3413c, postalCode=110002, st=Delhi,
serialNumber=e97f241aa0c0bba41522525f
fca6709074b4997eb02f4b93cdd87ef28ade
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Date: 2022.04.07 14:07:14 +05'30'

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 1.34 mg/ml
Therapeutic class:	Anti-Diabetic
Dosage form:	Solution for injection
Composition:	Water for Injections = 1.0000 Volume/Volume (V/v) U.S.P., J.P., Ph. Eur Inactive Sodium Hydroxide 2N = 1.0000 q.s. U.S.P., J.P., Ph. Eur Inactive Hydrochloric acid 2N = 1.0000 q.s. U.S.P., J.P., Ph. Eur Inactive Phenol = 5.5000 mg/ml U.S.P., J.P., Ph. Eur Inactive Propylene glycol = 14.0000 mg/ml U.S.P., J.P., Ph. Eur Inactive Disodium hydrogenphosphate, dihydrate = 1.4200 mg/ml

File No. CT/152/21-DCG(I)

	U.S.P., Ph. Eur Inactive Semaglutide = 1.3400 mg/ml In House Specification Active
Indications:	Type 2 Diabetes Mellitus and Peripheral Arterial Disease

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Shree Mahavir Health and Medical Relief Society, Shri Bachubhai Dahyabhai Mehta Mahavir Heart Institute, Shree Mahavir Health Campus, Athwagate, Ring Road, Surat-395001, Gujarat, India	Shri B D Mehta Mahavir Heart Institute Ethics Committee, Shree Mahavir Health Campus, Athwagate, Opp, Vanita Vishram Ground, Athwagate, Ring Road, Surat-395001, Gujarat, India ECR/850/Inst/GJ/2016/RR-20	Dr. Atul Damodar Abhyankar
2.	Research Cell, Dept. Of Cardiology, S.P. Medical College, Bikaner, Rajasthan, India-334003	Ethics Committee. S.P. Medical College. Bikaner, Rajasthan, India- 334003 ECR/27/SP/Inst/RJ/2013/RR-19	Dr. Devendra kumar Agarwal
3.	Sir Ganga Ram Hospital Department of Cardiology, Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi - 110060, India	Ethics Committee, Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi - 110060, India ECR/20/Inst/DL/2013/RR-19	Dr. Jitendra Pal Singh Sawhney
4.	Osmania Medical College & General Hospital, Afzalgunj, Hyderabad, T.S-500012	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad, Telangana-500095 ECR/300/Inst/AP/2013/RR-19	Dr. Krishna Mala Konda Reddy
5.	Shrikrishna Hrudayalaya and Critical care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012	Virtuous Institutional Medical Research Ethics Committee, IVth Floor Shrikrishna Hrudayalaya and Critical care Centre, Tikekar Road, Congress Nagar Square, Dhantoli, Nagpur-440012 ECR/548/Inst/MH/2014/RR-20	Dr. Mahesh Fulwani

File No. CT/152/21-DCG(I)

6.	VMMC & Safdarjung Hospital, New Delhi-110029	Institutional Ethics Committee, VMMC & Safdarjung Hospital, Room No. 505 & 506, 5 th Floor, Main OPD Building, VMMC & Safdarjung Hospital, New Delhi-110029 ECR/593/Inst/DL/2014/RR-20	Dr. Sandeep Bansal
7.	Vijan Hospital & Research Centre (Vijan Cardiac & Critical Care Centre), Dr Vijan Hospital Marg, College Road, Nashik- 422005, Maharashtra, India	Vijan Hospital Ethics Committee, Vijan Cardiac & Critical Care Centre, Dr Vijan Hospital Marg, College Road, Nashik- 422005, Maharashtra, India ECR/406/Inst/MH/2013/RR-19	Dr. Vinodkumar M, Vijan
