File No. CT/174/22-DCG(I)

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

सत्यमेव जयते

File No. CT/22/000174

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/2022/35319 (GCT/174/22) dated 21-12-2022, please find enclosed herewith the permission in Form CT-06 for conduct of Phase 3a clinical trial titled, "**The cardiovascular safety of cagrilintide 2.4 mg s.c. in combination with semaglutide 2.4 mg s.c. (CagriSema 2.4 mg/2.4 mg s.c.) once-weekly in participants with obesity and established cardiovascular disease", Protocol No.: NN9838-4942 Version No. 1.0, dated 22/08/2022 with a total of up-to 264 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:-

1) **Each subject should be provided glucometer and also calcitonin level atbaseline assay should be performed at a periodic interval;**
2) 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;
3) 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;
4) 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;

5) 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;

6) 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;

7) 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;

8) 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;

9) 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;

10) 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;

11) 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;

12) 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;

13) 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;

14) 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;

15) 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;

16) 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;

17) 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;

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

19) 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;

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,

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
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(D. Rajeev Singh Raghuvanshi)
Drugs Controller General (India) &
Central Licencing Authority

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File No. CT/174/22-DCG(I)

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 No.: NN9838-4942 Version No. 1.0, dated 22/08/2022** 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
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(Dr. Rajeev Singh Raghuvanshi)
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	CagriSema (0.25 mg/0.25 mg) / placebo CagriSema (0.5 mg/0.5 mg) / placebo CagriSema (1.0 mg/1.0 mg) / placebo CagriSema (1.7 mg/1.7 mg) / placebo CagriSema (0.25 mg/0.25 mg) / placebo
Therapeutic class:	Anti-obesity and Antidiabetic
Dosage form:	Solution for injection
Composition:	**Active substance:** Cagrilintide Semaglutide **Excipients:** L-Glutamic Acid Glycerol Hydrochloric Acid Sodium Hydroxide WFI Disodium phosphate, dehydrate

	Sodium Chloride L-Histidine
Indications:	Obesity and Diabetes mellitus

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Kamalnayan Bajaj Hospital, Gut no. 43, Satara Parisar, Beed bypass road, Aurangabad-431010, Maharashtra, India	Ethics Committee Kamalnayan Bajaj Hospital, Gut no.43, Satara Parisar, Beed bypass road, Aurangabad-431010, Maharashtra, India ECR/444/Inst/MH/2013/RR-20	Dr. Ajit Raghunath Bhagwat
2.	Narayana Institute of Cardiac Sciences, Narayana Hrudayalaya Limited-Unit of Narayana Health, No.258/A, Bommasandra Indl Area, Hosur Road, Anekal Taluk, Bangalore-560099	Narayana Health Medical Ethics Committee, Narayana Hrudayalaya Limited, 258/A, Bommasandra Indl Area, Hosur Road, Anekal Taluk, Bangalore-56009 ECR/390/Inst/KA/2013/RR-19	Dr. Basavaraj G. S
3.	KG Hospital, A Unit Of K Govindaswamy Naidu Medical Trust, No 5 Arts College Road, Coimbatore 641018, Tamil Nadu, India	Institutional Ethics Committee, KG Hospital, A Unit Of K Govindaswamy Naidu Medical Trust, No 5 Arts College Road Coimbatore Coimbatore Tamil Nadu – 641018, Tamil Nadu, India ECR/213/Inst/TN/2013/RR-19	Dr. Girithara Gopalakrishnan Jayaram Naidu
4.	Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab, India 141008	Institutional Ethics Committee, C/O Principal Office, Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab, India 141008 ECR/120/Inst/PB/2013/RR-19	Dr. Jubbin Jagan Jacob
5.	Department of Cardiology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh - 202002, Uttar Pradesh, India	Institutional Ethics Committee, Jawaharlal Nehru Medical College & Hospital, Aligarh Muslim University, Civil Line, Koil, Aligarh - 202002, Uttar Pradesh, India ECR/1418/Inst/UP/2020	Dr. Rabbani Muzaffar Uraj

6.	Apollo Excelcare Hospital (A unit of Asclepius Hospitals) Paschim Boragaon, Near Ganesh Mandir, NH 37, Guwahati, Dist. Kamrup, Metropolitan, Assam 781033, India	Institutional Ethics Committee, Excelcare Hospital, Paschim Boragaon, Near Ganesh Mandir, NH 37. Guwahati Kamrup Metropolitan. Assam-781033, India ECR/1230/Inst/AS/2019/RR-22	Dr. Manash P Baruah
7.	Chopda Medicare and Research Centre Pvt. Ltd., Magnum Heart Institute, 3/5, Patil Lane No. 1, Laxmi Nagar, Near K.B.H. Vidyalaya, Canada Corner, Nashik-422005, Maharashtra, India Chopda Medicare and Research Centre Pvt. Ltd., Magnum Heart Institute, Clinical Research Department, Flat No. 10, Laxmanrekha Apartment, Behind Magnum Heart Institute, Patil Lane No. 1, Canada Corner, Nashik-422005, Maharashtra, India	Magna-Care Ethics Committee, Chopda Medicare & Research Centre Pvt. Ltd; Magnum Heart Institute, Canada Corner, Nashik, Maharashtra-422005, India ECR/79/Inst/MH/2013/RR-19	Dr. Chopada Manojkumar Bhavarilal
8.	Omega Hospitals (P) Ltd., Mahaveer Circle, Kankanady, Mangalore 575 002, Karnataka, India	Omega Ethical Committee, Omega Hospitals (P) Ltd. Mahaveer Circle, Kankanady, Mangalore 575 002, Karnataka, India ECR/89/Inst/KA/2013/RR-20	Dr Mukund Kumbla
9.	Rhythm Heart Institute- A Unit of Synergy Lifecare Pvt. Ltd., Near Siddharth Bunglows, Sama- Savli Road, Vadodara-390022 Gujarat	Rhythm Heart Institute Ethics Committee, Near Siddharth Bunglows, Sama- Savli Road, Vadodara- 390022, India ECR/224/Inst/GJ/2013/RR-19	Dr. Nirav Chandulal Bhalani
10.	Room No. 434, Cardiology Department, C Block, OPD Building, AIIMS Jodhpur 342005 Rajasthan, India	Institutional Human Ethics Committee, All India Institute of Medical Sciences, Basni Jodhpur, Rajasthan – 342005, India Room no. 332, Research Section, Third Floor, Medical College Building, AIIMS, Jodhpur, Rajasthan – 342005, India	Dr. Rahul Choudhary

		ECR/866/Inst/RJ/2016/RR-19	
11.	Dr. B.L. Kapur Memorial Hospital, Pusa Road, New Delhi-110005, India	Dr. B. L. Kapur Memorial Hospital Ethics Committee, Dr. B. L. Kapur Memorial Hospital, Academic Affairs Research and Continuing Education, Pusa Road, Rajendra Place, New Delhi - 110005 India ECR/3/BLK/Inst/DL/2013/RR-19	Dr. Satbir Singh
12.	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli road, Lucknow U.P. 226014	INSTITUTIONAL ETHICS COMMITTEE, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Ra ebareli Road, Lucknow, Uttar Pradesh - 226014 India ECR/16/Inst/UP/2013/RR-20	Dr. Sudeep Kumar
13.	Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi - 110060, India	Sir Ganga Ram Hospital Ethics Committee, Room No. 1643, 6th Floor, Causality Building, Sir Ganga Ram Hospital, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi-110060, India ECR/20/Inst/DL/2013/RR-19	Dr. Sudhir Tripathi
14.	K.R. Hospital attached Mysore Medical College and Research Institute, Irwin Road, Mysore, Karnataka 570001, India	Institutional Ethics Committee - Mysore Medical College and Research Institute and Associated Hospitals, Department of Pathology, KR Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysuru - 570001, Karnataka, India ECR/134/Inst/KA/2013/RR-19	Dr Sumaiya Anjum
15.	Marengo CIMS Hospital Pvt Ltd., Plot no 67/1, Opp. panchamrut bunglows, Near shukan mall, Off. Science city Road, Sola, Ahmedabad - 380060, Gujarat, India	Ethics Committee Of Care Institute Of Medical Science, Marengo CIMS Hospital Pvt Ltd., Plot no 67/1, Opp. panchamrut bunglows, Near shukan mall, Off. Science city Road, Sola, Ahmedabad - 380060, Gujarat, India ECR/206/Inst/GJ/2013/RR-20	Dr. Urmil Shah

16.	Kumudini Devi Diabetes Research Center, Ramdevrao Hospital (A unit of Sivananda Rehabilitation Home) Kukatpally, Hyderabad-500072. Telangana. India	Institutional Ethics Committee, Ramdevrao Hospital (A unit of Sivananda Rehabilitation Home), Kukatpally, Hyderabad, Telangana - 500072 India ECR/709/Inst/TG/2015/RR-21	Dr. Paturi Vishu Priya Rao
17.	Sassoon General Hospitals, Jayprakash Narayan Road, Near Pune Railway Station, Pune, Maharashtra, India 411001	IEC of B.J.G.M.C And Sassoon General Hospital, Pune, Department of Pharmacology, B.J. Government Medical College, Pune Railway Station Road, Pune, Maharashtra - 411001 India ECR/280/Inst/Maha/2013/RR-19	Dr. Kokane Hemant Trimbak
18.	G.B Pant Institute Of Post Graduate Medical Education And Research, 1, Jawaharlal Nehru Marg, 64 Khamba, Raj Ghat, New Delhi, Delhi-110002	Institutional Ethics Committee, 3rd Floor, Room No 306A, Maulana Azad Medical College, Bahadur Shah Zafer Marg, New Delhi - 110002 India ECR/329/Inst/DL/2013/RR-19	Dr. Mohit D. Gupta
19.	Seminar Room, AB 6 Ward, 6th Floor, Ward Block, AIIMS, Ansari Nagar, New Delhi - 110029	Institute Ethics Committee, Room no. 102, 1st Floor, Old OT Block, All India Institute of Medical Scieces, Ansari Nagar, New Delhi 110029, India ECR/538/Inst/DL/2014/RR-20	Dr. Nikhil Tandon
20.	All India Institute of Medical Sciences, Plot No. 2, Sector - 20, MIHAN, Nagpur, Maharashtra, 441108, India	Institutional Ethics Committee, AIIMS, Plot No. 2, Sector - 20, 1st Floor, OPD Building, MIHAN, Nagpur, Maharashtra, 441108, India ECR/1392/Inst/MH/2020	Dr. Sagar Makode
21.	Dept Of Cardiology, King George's Medical University Chowk, Lucknow - 226003 Uttar Pradesh, India	Institutional Ethics Committee King Georges Medical University, Office of Research Cell, Lucknow, Uttar Pradesh - 226003 India ECR/262/Inst/UP/2013/RR-19	Dr. S. K. Dwivedi

File No. CT/174/22-DCG(I)

22.	Indraprastha Apollo Hospital, Sarita Vihar, Mathura Road, New Delhi - 110076, India	Institutional Ethics Committee - Clinical Studies, Indraprastha Apollo Hospitals, Sarita Vihar, Mathura Road, Delhi - 110076, India ECR/5/Inst/DL/2013/RR-19	Dr. Rajeeve Kumar
23.	Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi 110060, India	Sir Ganga Ram Hospital Ethics Committee, Sir Ganga Ram Hospital, Old Rajinder Nagar, New Delhi-110060, India ECR/20/Inst/DL/2013/RR-19	Dr. Anurag Gupta
24.	Sunrise Hospitals (A Unit of NS Health Care Services Pvt Ltd), #33-25-35 Near Pushpa Hotel Centre, Opp. Corporation Bank, Bellapu Sobhanadri Road, Vijayawada - 520002, Andhra Pradesh, India	Institutional Ethics Committee Sunrise Hospitals (A Unit of NS Health Care Services Pvt Ltd), #33-25-35 Near Pushpa Hotel Centre, Opp. Corporation Bank, Bellapu Sobhanadri Road, Vijayawada - 520002, Andhra Pradesh, India ECR/756/INST/AP/2015/RR-21	Dr. Krishna M VS

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