



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  
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**File No. CT/23/000083**

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/2023/38413 (GCT/83/23) dated 06-07-2023, please find enclosed herewith the permission in Form CT-06 for conduct of Phase 3a clinical trial titled, "**Efficacy and safety of co-administered cagrilintide and semaglutide (CagriSema) s.c. in doses 2.4/2.4 mg and 1.0/1.0 mg once weekly versus semaglutide 2.4 mg and 1.0 mg, cagrilintide 2.4 mg and placebo in participants with type 2 diabetes inadequately controlled on metformin with or without anSGLT2 inhibitor**", Protocol No.: NN9388-4896 Version No. 1.0, dated 24/04/2023 with a total of up-to 110 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) **Final report of carcinogenicity study shall be submitted;**
- 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;

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- 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 Licencing Authority and may be used for test or analysis of any drug for and on behalf of Central Licencing 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.



**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.: NN9388-4896 Version No. 1.0, dated 24/04/2023** 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  
DN: cn=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62fa23e4eafbe8a239774cceb03c2769041015a06564fe6754b765db1cb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI  
Date: 2023.12.28 10:27:32 +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:

<b>Names of the new drug or investigational new drug</b>	CagriSema 1.0 mg/ml + 0.5 mg/ml (0.25 mg/0.25 mg) / cagrilintide 1.0 mg/ml (0.25 mg) / semaglutide 0.5 mg/ml (0.25 mg) / placebo
	CagriSema 2.0 mg/ml + 1.0 mg/ml (0.5 mg/0.5 mg) / cagrilintide 2.0 mg/ml (0.5 mg) / semaglutide 1.0 mg/ml (0.5 mg) / placebo
	CagriSema 4.0 mg/ml + 2.0 mg/ml (1.0 mg/1.0 mg) / cagrilintide 4.0 mg/ml (1.0 mg) / semaglutide 2.0 mg/ml (1.0 mg) / placebo
	CagriSema 6.8 mg/ml + 3.4 mg/ml (1.7 mg/1.7 mg) / cagrilintide 6.8 mg/ml (1.7 mg) / semaglutide 3.4 mg/ml (1.7 mg) / placebo
	CagriSema 9.6 mg/ml + 4.8 mg/ml (2.4 mg/2.4 mg) / cagrilintide 9.6 mg/ml (2.4 mg) / semaglutide 4.8 mg/ml (2.4 mg) / placebo

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Details of clinical trial site:

<b>Sr. No.</b>	<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
1.	Department of Clinical Trials & Research, Apollo Multispeciality Hospitals Limited, 58, Canal Circular Road Kolkata -700054, West Bengal, India	Institutional Ethics Committee, Apollo Multispeciality Hospitals Limited 58, Canal Circular Road Kolkata 700054  ECR/373/Inst/WB/2013/RR-19	Dr. Tirthankar Chaudhary
2.	KG Hospital, A unit of K. Govindaswamy naidu medical Trust, No 5 Govt Arts College Road, Coimbatore 641018, Tamil Nadu, India	Institutional Ethic Committee KG Hospital, K. Govindaswamy Naidu Medical Trust, No 5 Govt Arts College Road Coimbatore, Tamil Nadu -641018, India  ECR/213/Inst/TN/2013/RR-19	Dr. Girithara Gopalakrishnan Jayaram Naidu
3.	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-500072 Telangana. India  ECR/709/Inst/TG/2015/RR-21	Dr. Paturi Vishnupriya Rao
4.	Room no. 1014, Department of Medicine, Academic Block, Lady Hardinge Medical College C-604, Shaheed Bhagat Singh Road, DIZ Area, Connaught Place, New Delhi-110001	Institutional Ethics Committee, Lady Hardinge Medical College & Associated Hospital, Room No. 625, Academic Block, 6 <sup>th</sup> Floor, New Delhi 110001  ECR/435/Inst/DL/2013/RR-20	Dr. Anupam Prakash
5.	Yalamanchi Hospitals and Research centre Pvt. Ltd., D. No. 29-7-44, Venkataratnam street, Suryaraopet, Vijaywada, Andhra Pradesh, 520002, India	Yalamanchi Hospital Ethics Committee D No: 29-7-44, Venkataratnam street, Suryaraopet, Vijayawada, Andhra Pradesh-520002, India  ECR/564/Inst/AP/2014/RR-20	Dr. Aiswarya Yalamanchi

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6.	Lifecare Hospital and Research Centre, #2748/2152, M.L.N Enclave, 16th 'E' Cross Road, 8th Main, D Block, Next to Corporation bank, Sahakarnagar, Bangalore-560092	Life Care Hospital Institutional Review Board, #2748/2152, M.L.N Enclave, 16th 'E' Cross Road, 8th Main, D Block, Next to Corporation bank, Sahakarnagar, Bangalore-560092  ECR/883/Inst/KA/2017/RR-20	Dr. Sreenivasamurthy L
7.	K R Hospital attached to Mysore Medical College and Research Institute, Irwin Road, Mysuru- 570001	Institutional Ethics Committee Mysore Medical College & Research Institute and Associated Hospitals, Dept of Pathology, K R Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysuru- 570001  ECR/134/Inst/KA/2013/RR-19	Dr. Sumaiya Anjum
8.	Gleneagles Global Hospital, 1st floor, 6-1-1070/1 to 4, Lakdikapool, Hyderabad-500004	Institutional Ethics Committee Gleneagles Global Hospital, 6-1-1070/1 to 4, Lakdikapool, Hyderabad- 500004, Telangana, India  6-2-1/14, Opposite Saifabad Police Station, Lane adjacent to HP petrol bunk, Lakdikapool, Hyderabad-500004, Telangana, India  ECR/158/Inst/AP/2013/RR-19	Dr. Lakshmi Lavanya Alapati
9.	Madras Diabetes Research Foundation, No. 4 Conran Smith Road, Gopalapuram, Chennai - 600086	Institutional Ethics Committee of Madras Diabetes Research Foundation, Madras Diabetes Research Foundation, No. 4 Conran Smith Road, Gopalapuram, Chennai - 600086  ECR/194/Inst/TN/2013/RR-19	Dr. V Mohan
10.	Swasthya Diabetes Care, Opp Jaymangal BRTS Bus Stop, 132 Feet Ring Road, Naranpura, Ahmedabad-380013, Gujarat	OM Institutional Ethics Committee OM Children Hospital, 304-405, Silver Star Commercial Complex Silver Star Cross Road, New Chandlodia, Ahmedabad, Gujarat, India- 382481  ECR/1168/Inst/GJ/2018/RR-	Dr. Mayur Ramanlal Patel

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11.	Ashirwad Hospital and Research Centre, Maratha Section, Near Jijamata Udyan, Ulhasnagar, Thane, Maharashtra –421004	Ashirwad Hospital Ethics Committee, Ashirwad Hospital and Research Centre, Maratha Section, Near Jijamata Udyan Ulhasnagar, Thane, Maharashtra - 421004 India  ECR/247/Inst/MH/2013/RR-19	Dr. Shrikant Vishnu Deshpande
12.	Gauhati Medical College, Guwahati, Indrapur Bhangagarh, Guwahati – Kamrup (Metro), Assam-781032	Institutional ethics committee GMCH, Indrapur, Narakasur HillTop, Gauhati Medical College, Bhangagarh, Guwahati, Assam- 781003  ECR/1470/Inst/AS/2020	Dr. Anjan Jyoti Talukdar
13.	Department of Endocrinology, Room No. 10, Nehru Extension, Postgraduate Institute of Medical Education and Research (PGIMER) Sector -12 ,Chandigarh-160012	Institutional Ethics Committee Room No. 6006, P N Chuttani Block, Research Block, Sector-12, Chandigarh-160012  ECR/25/Inst/CH/2013/RR-20	Dr. Rama Walia
14.	SMS Medical College & Attached Hospitals, Department of Medicine, G-1,Dhanvantri OPD Block, SMS Hospital Jaipur-302004 Rajasthan	Ethics Committee S.M.S. Medical College and Attached Hospitals J.L.N. Marg Jaipur, 302004, Rajasthan  ECR/26/Inst/RJ/2013/RR-19	Dr. Abhishek Agrawal
15.	Department of Endocrinology, 4th floor, room no. 419, College building, T.N. BYL Nair Hospital and T N Medical College and BYL Nair Ch. Hospital, Dr A. L. Nair Road, Mumbai-400008	Institutional Ethics Committee, 'G' building, Ground Floor, B.Y.L Nair Ch. Hospital, Dr. A. L. Nair Road, Mumbai - 400 008  ECR/22/Inst/Maha/2013/RR-19	Dr. Nikhil Madhusudan Bhagwat

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