



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/23/000147

To,

M/s Novo Nordisk India Private Limited,
Nxt Tower-2, Floor 1&2, Embassy Manyata BusinessPark,
Nagavara Village, Kasaba Hobli, Bangalore-560045, India.

Sir,

With reference to your application No. GCT/CT04/FF/2023/40531 (GCT/147/23) dated 17-11-2023, 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) 2.4mg/2.4mg s.c. once weekly versus tirzepatide 15 mg s.c. once weekly in participants with type 2 diabetes inadequately controlled on metformin with or without an SGLT2 inhibitor"**, Protocol No.: NN9388-4894 Version No. 1.0 Protocol Date 21-JUN-2023 with a total of up-to 200 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) 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;
- 2) 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;
- 3) 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;
- 4) 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;

- 5) 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;
- 6) 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;
- 7) 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;
- 8) 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;
- 9) 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;
- 10) 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;
- 11) 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;
- 12) 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;
- 13) 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;
- 14) 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;
- 15) 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;
- 16) 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;
- 17) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

- 18)** 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;
- 19)** 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,

(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 Novo Nordisk India Pvt. Ltd, NxtTower-2, Floor 1&2, Embassy Manyata Business Park, Nagavara Village, Kasaba Hobli, Bangalore- 560045 India Telephone No.:+91 8040303200FAX: +91 8041123518 E-Mail:NHMK@NOVONORDISK.COM** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: NN9388-4894 Version No. 1.0 Protocol Date 21-JUN-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 _____

(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	CagriSema 1.0 mg/ml + 0.5 mg/ml (0.25 mg/0.25 mg) CagriSema 2.0 mg/ml + 1.0 mg/ml (0.5 mg/0.5 mg) CagriSema 4.0 mg/ml + 2.0 mg/ml (1.0 mg/1.0 mg) CagriSema 6.8 mg/ml + 3.4 mg/ml (1.7 mg/1.7 mg) CagriSema 9.6 mg/ml + 4.8 mg/ml (2.4 mg/2.4 mg)
Therapeutic class:	Anti-diabetic
Dosage form:	Solution for injection
Composition:	-
Indications:	Type 2 Diabetes

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Maulana Azad Medical College, Room No 103-104. Department of Medicine, BL Taneja Block, Maulana Azad Medical College, New Delhi 110002	Institutional Ethics Committee, Room No. 306 B, 3rd Floor, Maulana Azad Medical College, New Delhi 110002 ECR/329/Inst/DL/2013/RR-19	Dr Sandeep Garg
2.	Nirmal Hospitals Pvt. Ltd., 5th Floor, Clinical Research Room, Wing A, Sagrampura, Surat - 395002, Gujarat	Nirmal Hospital Pvt Ltd, Majura Gate, Ring road, Sagrampura, Surat – 395002, Gujarat, India ECR/390/Inst/GJ/2013/RR-19	Dr. Piyush Desai
3.	SMS Hospital, Department of Endocrinology, Room No.43, A Fourth floor, Dhanvantri OPD Block, SMS Hospital, Jaipur, Rajasthan- 302004	Ethics Committee SMS Medical college & Attached Hospitals Jaipur-302004 ECR/26/Inst/RJ/2013/RR-19	Dr Balram Sharma
4.	Christian Medical College, 810, Department of Endocrinology Diabetes & Metabolism, Christian Medical College, Vellore, Tamil Nadu, India- 632002	Institutional Review Board-Silver, Christian Medical College, Bagayam, Vellore, Tamil Nadu, India- 632002 ECR/326/TN 2013/RR-16	Dr. Nitin Kapoor
5.	BSES MG Hospital, Opp. Railway Station, SV Road, 7th floor, inside waiting area, Andheri West, Mumbai, Maharashtra- 400058	BSES Municipal General Hospital Ethics Committee, S.V. Road, Opp. Railway Station, Andheri West, Mumbai- 400058 ECR/343/Inst/MH/2013/RR-19	Dr. Manoj Chawla
6.	Jothydev's Diabetes Research Centre, JDC Junction, Konkalam Road, Department of research, Room no 25, second floor, Mudavanmugal, Poojappura, Trivandrum, Kerela, India- 695032	Jothydev's Diabetes Research Centre, JDC Junction, Mudavanmugal, Poojappura, Trivandrum, Kerela- 695032 ECR/1167/Inst/KL/2019/RR-22	Dr. Jothydev Kesavadev

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7.	Belgaum Diabetes Centre, Second floor, Maruti Street, Belgaum, Karnataka- 590001	Lakeview Ethics Committee, CTC No- 5653/1720, Mahatma Phule Road, Shahpur, 590003 ECR/1586/INST/KA/2021	Dr. Neeta Deshpande
8.	Diabetes, Thyroid and Endocrine centre, A- 1, Madrampura, third floor, Department of Clinical Research, Near 4 no. ESI Hospital, Ajmer Road, Jaipur-Rajasthan, India- 302006	Human Welfare Ethical Committee for Human Sciences and Research Address- A-1, Madrampura, Near 4 No. ESI Hospital, Ajmer Road, Sodala, Jaipur, Rajasthan- 302006 ECR/36/Inst/RJ/2013/RR-19	Dr. Surendra Sharma
9.	Seth GS Medical College & KEM Hospital, Room 6, 1st Floor, Clinical Research Department, Mumbai, Maharashtra, India- 400012	New UG/PG Hostel, 20 storey Hostel Building, Ground Floor, KEM Hospital Campus, Near Main boys hostel, Dr. S. S. Rao Marg, Parel, Mumbai – 400012, India ECR/229/Inst/MH/2013/RR-19	Dr. Saba Memon
10.	Government Institute of Medical Sciences, Department of medicine, Government Institute of Medical Sciences, near Gautam Buddha University, Delhi NCR, Kasna Village, Greater Noida, Uttar Pradesh, India- 201310	Government Institute of Medical Sciences, Greater Noida, Gautam Buddha Nagar, U.P., India, 201310. ECR/1224/Inst/UP/2019/RR-22	Dr. Saurabh Srivastava
11.	Rajiv Gandhi Centre for Diabetes and Endocrinology, J.N Medical College, Aligarh Muslim University, Aligarh, Uttar Pradesh, India- 202002	Institutional Ethic Committee (IEC), J.N. MEDICAL COLLEGE HSOPITAL, ALIGARH MUSLIM UNIVERSITY, ALIGARH ECR/1418/Inst/UP/2020	Dr. Hamid Ashraf
12.	SRM Centre for Clinical Trials & Research, 3rd Floor, SRM Medical College Hospital & Research Centre, Kattankulathur, Tamil Nadu- 603 203	ETHICS COMMITTEE, SRM MEDICAL COLLEGE HOSPITAL, SRM NAGAR, POTHERI, KATTANKULATHUR, CHENGALPATTU – 603203 ECR/431/Inst/TN/2013/RR-19	Dr. J.S Kumar

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13.	BP Poddar Hospital, 71/1, Humayun Kabir Sarani, Durgapur Colony, Block- G, New Alipore, Kolkata, West Bengal, India- 700053	B P Poddar & Parvati Devi Foundation For Education , 71/1, Humayun Kabair Sarani, Block-G, New Alipore, Kolkata-700053 ECR/1812/Inst/WB/2023	Dr. Debaditya Das
14.	AIG Hospitals, 1st floor, Cluster K, Obesity and Metabolic Therapy Department, Beside Ramky towers, Mindspace road, Gachibowli, Telangana, India- 500032	Institutional Ethics Committee Gleneagles Global Hospitals ECR/346/Inst/AP/2013/RR-22	Dr Abhishek Katakwar
15.	TOTALL Diabetes Hormone Institute, BCM Health Island, PU4, Scheme 54, Behind Prestige Management Institute, Near Bombay Hospital, Indore, Madhya Pradesh, India- 452010	Ethics Committee of Diabetes Thyroid Hormone Research Institute TOTALL DIABETES HORMONE INSTITUTE BCM Health Island, PU4, Scheme 54, Behind Prestige Management Institute, Near Bombay Hospital, INDORE – 452010 (Madhya Pradesh) India ECR/409/Inst/MP/2013/RR-19	Dr. Sunil Jain
16.	Grant Medical Foundation Ruby Hall Clinic, Clinical Research Department E4- C to E4- F, 4th floor, Grant Medical Foundation Ruby Hall Clinic, Fifth Avenue Condominium,, Dhole Patil Road, Pune, Maharashtra, India- 411001	Institutional Ethics Committee Poona Medical Research Foundation, E- 4 C to E- 4 F, 4th Floor, Fifth Avenue Condominium Dhole Aptil Road, Pune- 411001, Maharashtra, India ECR/24/Inst/MH/2013/RR-22	Dr. Sanjay Agarwal
17.	Endolife Specialty Hospitals Pvt. Ltd. , D. No. 12-12-94, Old Club Road, Kothapet, Guntur, Andhra Pradesh, India- 522001	ENDOLIFE SPECIALITY HOSPITALS PVT LTD DNO.12-12-94, OLD CLUB ROAD, KOTHAPET, GUNTUR-522001, ANDHRA PRADESH, INDIA. ECR/647/Inst/AP/2014/RR-20	Dr. Kongara Srikanth

18.	Government (Calicut) Medical College, Clinical Research room, Department of General Medicine, opposite OP pharmacy, Medical College junction, 17, Mavoor road, near police station, Calicut Medical College, Kozhikode, Kerala, India- 673008	Institutional Ethics Committee Government Medical College, Kozhikode Room No. 1 & 2, Ground Floor, Lecture Theatre Complex Medical College Campus, Medical College P.O, Calicut-673008, Kerala ECR/395/Inst/KL/2013/RR-20	Dr. Chandni R
19.	Osmania General Hospital, Dept of Endocrinology, Clinical Research Room, 2nd floor, Begum Bazar, Afzal Gunj, Telangana, India- 500012	Institutional Ethics Committee Osmania Medical College, Osmania Medical College, Koti, Hyderabad-500095, telangana, India ECR/300/Inst/AP/2013/RR-19	Dr. Rakesh Sahay
20.	P D Hinduja National Hospital and Medical Research Centre, #2214, second floor, P D Hinduja National Hospital and Medical Research Centre, Veersarverkar Marg, Mahim (west), Mumbai, Maharashtra, India- 400016	Institutional Ethics Committee P D Hinduja Hospital and Medical Research Centre, 913, 9th floor, Research Dept., Lalita Girdhar (S1) bldg., T H Katariya Marg, Mahim Mumbai Mumbai City, Maharashtra - 400016 India EC/RENEW/INST/2019/3409	Dr. Manoj Chadha
21.	Indian Institute of Diabetes, Pulayanarkotta, Thiruvananthapuram, Kerala, India- 695033	Institutional Ethic Committee, Indian Institute of Diabetes, Pulayanarkotta, Trivandrum- 695031, Kerala. ECR/688/Inst/KL/2014/RR-20	Dr. P. K. Jabbar
22.	All India Institute of Medical Sciences (AIIMS), New Delhi, Room No.305, 3rd floor, Biotechnology block, Department of Endocrinology & Metabolism, Ansari Nagar, New Delhi, India- 110029	Institutional Ethics committee for biomedical and health research, All India Institute Of Medical Sciences, Old OT block, Room No. 102, , AIIMS Hospital, Ansari Nagar, New Delhi- 110029 ECR/538/Inst/DL/2014/RR-20	Dr. Yashdeep Gupta
23.	Gandhi Hospital & Medical college, Department of Endocrinology, 3rd floor, Gandhi Hospital & Medical college, Musheerabad, Secunderabad, Telangana, India-500003	INSTITUTIONAL ETHICS COMMITTEE, GANDHI MEDICAL COLLEGE AND HOSPITAL, MUSHEERABAD, SECUNDERABAD. 500006	Dr. Vijay Sekhar Reddy

		ECR/180/Inst/AP/2013/RR-19	
24.	Chellaram Diabetes Institute, 1st floor, Lalani Quantum, Bavdhan (Budruk), Pune-Bangalore National Highway No. 4, Pune, Maharashtra, India- 411021	ChellaramDiabetes Institute Ethics CommitteeChellaram Diabetes Institute,1st floor, Lalani Quantum Pune - Bangalore National Highway No. 4, Bavdhan (Budruk), Pune, Maharashtra – 411021 ECR/203/Inst/MH/2014/RR-20	Dr. Unnikrishnan A.G
25.	M S Ramaiah Memorial Hospital, M S Ramaiah Clinical Research Center, 1st floor, M S Ramaiah Advanced Learning Center, Gate-4, Gagangothri campus, MSRIT Post, New BEL Road, Bangalore, Karnataka-560054	M S Ramaiah Medical College , M S Ramaiah Nagra, MSRIT Post, Bengaluru 560054 ECR/215/Inst/KA/2013/RR-22	Dr. Chitra Selvan
26.	Noble Hospital Pvt. Ltd., 153A Magarpatta City Road, Hadapsar, Pune, Maharashtra- 411013	Noble Hospital Clinical Research Department, Basement, Noble Annex, Noble Hospital Pvt. Ltd. 153 A, Magarpatta City Road, Pune-411013. Maharashtra, India ECR/259/Inst/MH/2013/RR-19	Dr. Reema Kashiva
27.	Sir Ganga Ram Hospital, Clinical Research Room, 1st Floor, Near Male General Ward, Sir Ganga Ram Hospital Marg, Rajinder Nagar, New Delhi - 110060, India	Sir Ganga Ram Hospital Ethics Committee Room no 1643, 6th Floor, Causality Building, Old Rajinder Nagar, Sir Ganga Ram Hospital, Sir Ganga Ram Hospital MargNew Delhi -110060India ECR/20/Inst/DL/2013/RR-19	Dr. Sudhir Tripathi
28.	Arthur Asirvatham Hospital, Ground floor, Clinical research department, No:42-A, Kuruvikaran Salai, Madurai, Tamil Nadu, India-625020	Institutional Ethics Committee, ARTHUR ASIRVATHAM HOSPITAL,42-A KURUVIKKARAN SALAI,NEAR ANNA BUSSTAND,MADURAI-	Dr. Arthur Asirvatham

		625020	
		ECR/186/Inst/TN/2013/RR19	
29.	Udayan Health Care Pvt. Ltd, 730, near Bangla Bazar, Eldeco Udyan-1, Bangla Bazar, Lucknow, Uttar Pradesh, India- 226002	730, Udyan-1 Eldico, Near Bangla Bazar, Lucknow, Uttar Pradesh 226002 ECR/1300/Inst/UP/2019	Dr. Mukulesh Gupta
30.	Eternal Heart Care Centre, Ground Floor, C-Block, Eternal Heart Care Centre, 3A, Jagatpura Road, Near Jawahar Circle, Jaipur, Rajasthan, India- 302017	ETERNAL HEART CARE CENTRE AND RESEARCH INSTITUTE, 3A, NEAR JAWAHAR CIRCLE, JAIPUR - 302017, RAJASTHAN, INDIA ECR/615/Inst/RJ/2014/RR-20	Dr. Sailesh Lodha
31.	M.V. Hospital for Diabetes Pvt Ltd, Clinical Research department, No.4, West Mada Church Street, Royapuram, Chennai, Tamil Nadu, India- 600013	Ethics Committee, Prof. M. Viswanathan Diabetes Research Centre M. V Hospital for Diabetes Pvt. Ltd. No.4, West madha church street, Royapuram, Chennai, Tamil Nadu, 600 013, India ECR/51/Inst/TN/2013/RR-19	Dr. Vijay Viswanathan
32.	SSG Hospital, Baroda, Sayajigunj, Jail Road, Vadodara, Gujarat, India- 390006	Institutional Ethics Committee for Human Research, Medical College, Baroda, Anandpura VadodaraVadodara Gujarat - 390001 India ECR/85/Inst/GJ/2013/RR-19	Dr. Keyur Brahme
33.	Excel Endocrine Centre, Diabetes Corner, 1758, E Ward, 4th Lane Rajarampuri, Kolhapur, Maharashtra, India- 416008	EXCEL ENDOCRINE CENTRE INSTITUTIONAL ETHICS COMMITTEE KOLHAPUR, 1758,E- WARD,4TH LANE RAJARAMPURI, KOLHAPUR-416008. MAHARASHTRA ECR/1406/Inst/MH/2020	Dr. Sharvil Gadve
34.	JLN Medical College, Clinical Research Department, Medicine College Building, Kala Bagh, Ajmer, Rajasthan- 305001	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer-305001 Rajasthan, India	Dr. Sanjiv Maheshwari

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