



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/22/000007

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/2022/30127 (GCT/07/22) dated 25-01-2022, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“A 52-week study comparing the efficacy and safety of once weekly IcoSema and once weekly insulin icodec, both treatment arms with or without oral anti-diabetic drugs, in participants with type 2 diabetes inadequately controlled with daily basal insulin. COMBINE 1”**, Protocol Number: **NN1535-4591 Protocol Version 3.0 dated 10-August-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) **The firm should conduct the study with initial 30 subjects and their interim analysis data should be submitted for review by CDSCO for further continuation of the study;**
- 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.

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- 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,

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

**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: NN1535-4591 Protocol Version 3.0 dated 10-August-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 _____

(Dr. V. G. Somani)
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	IcoSema 700U/ml+2mg/ml (Insulin icodec 700U/ml+Semaglutide 2mg/ml)
Therapeutic class:	Anti Diabetic
Dosage form:	Solution for injection
Composition:	Water for Injections(WFI) = 1.0000Volume/Volume(V/v) U.S.P., J.P., Ph. Eur Inactive Sodium hydroxide = q.s. U.S.P., J.P., Ph. Eur Inactive Hydrochloric acid = q.s. U.S.P.,J.P., Ph. Eur Inactive Sodium chloride = 1.1700 mg/ml U.S.P., J.P., Ph. Eur Inactive Metacresol = 1.0800 mg/ml U.S.P., Ph .Eur Inactive Phenol = 5.6500 mg/ml U.S.P., J.P., Ph. Eur Inactive Glycerol =15.0000 mg/ml U.S.P., J.P., Ph. Eur Inactive Zinc acetate =101.0000 µg/ml U.S.P., J.P., Ph. Eur Inactive Semaglutide = 2.0000 mg/ml In House Specification Active

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	Insulin icodec =4200.0000 nmol/mlIn House Specification Active
Indications:	Type 2 Diabetes Mellitus

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	PG Department of Medicine, Room No. 201, 2 nd Floor, New medicine Block, SCB. Medical College & Hospital, S.C.B. Medical College, Cuttack-753007, India	Institutional Ethics Committee SCB. Medical College and Hospital, Cuttack, - 753007 ECR/84/Inst/OR/2013/RR-30	Dr Jayanta Kumar Panda
2.	Department of Medicine, K.R. Hospital, Attached to Mysore Medical College and Research Institute, Irwin Road, Mysuru-, 570001, Karnataka, India	Institutional Ethics Committee- Mysore Medical College and Research Institute and Associated Hospitals, Mysore Medical College and Research Institute Irwin Road, Mysuru-, 570001, Karnataka, India ECR/134/Inst/KA/2013/RR-19	Dr Sumaiya Anjum
3.	Excel Endocrine Centre, Diabetes Corner, 1758, E-Ward, 4 th Lane, Rajarampuri, Kolhapur-416008, India	Excel Endocrine Centre Institutional Ethics Committee, Excel Endocrine Centre Diabetes Corner 1758, E-Ward 4th Lane, Rajarampuri, Kolhapur Maharashtra - 416008 ECR/1406/Inst/MH/2020	Dr Sharvil Suresh Gadve
4.	CIMETs Inamdar Mutispeciality Hospital, Sr. No .15, Fatima Nagar, Pune-411040	Ethics Committee Inamdar Multispeciality Hospital, CIMETs Inamdar Mutispeciality Hospital. Hospital Building Sr. .No .15, Fatima Nagar , Pune-411040 ECR/354/Inst/MH/2013/RR-20	Dr Kadam Yogesh Dasharath
5.	Bhaktivedanta Hospital & Research Institute, Srishti Complex, Bhaktivedanta Swami Marg Mira Road (E) Thane – 401107, Maharashtra, India	Bhaktivedanta Hospital Ethics Committee, Bhaktivedanta HEC Office, 6 th Floor, Bhaktivedanta Hospital and Research Institute, Srishti Complex, Bhaktivedanta Swami Marg Miraroad (E) Thane – 401107, Maharashtra, India	Dr Ameya Sudhakar Joshi

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		ECR/396/Inst/MH/2013/RR-19	
6.	M.V. Hospital for Diabetes Private limited, #4, West Madha Church Street, Royapuram, Chennai, Tamil Nadu - 600013, India	Prof. M. Viswanathan Diabetes Research Centre, #4, West Madha Church Street, Royapuram, Chennai, Tamil Nadu - 600013, India	Dr Vijay Viswanathan
		ECR/51/Inst/TN/2013/RR-19	
7.	Room No. 108, Department of Medicine, Academic Block, First Floor, Lady Hardinge Medical College, C-604, Shaheed Bhagat Singh Road, DIZ Area, Connaught place, New Delhi - 110001	Institutional Ethics Committee, Lady Hardinge Medical College and Associated Hospital, Room No. 625, Academic Block, 6 th Floor, New elhi-110001	Dr Anupam Prakash
		ECR/435/Inst/DL/2013/RR-20	
8.	Department of Endocrinology, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana-141001, Punjab	Drug Trial Ethics Committee, Basement Hero DMC heart Institute, Opp. Library, Dayanand Medical College and Hospital, Tagore Nagar, Civil Lines, Ludhiana, Punjab - 141001, India	Dr Parminder Singh
		ECR/101/Inst/PB/2013/RR-19	
9.	Post Graduate Institute of Medical Education & Research, Chandigarh, Nehru Extension Block, Ground Floor, Room No. 08, PGIMER, Chandigarh-160012	Institutional Ethics Committee, Room No. 6006, IEC Office A, 6th Floor, P N Chuttani Block Tel-5266	Dr Sanjay Kumar Bhadada
		ECR/25/Inst/CH/2013/RR-20	
10.	Department of Endocrinology, 2 nd Floor, OP building, Room Number: 31 0, Osmania General Hospital, Afzalgunj, Hyderabad-500012 Telangana, India	Institutional Ethics Committee Osmania Medical College, Osmania Medical College, Koti, Hyderabad - 500 095, Telangana, India	Dr K. Neelaveni
		ECR/300/Inst/AP/2013/RR-19	
11.	Excelcare Hospitals, (Unit of Asclepius Hospital and Healthcare Private Ltd.) Paschim Boragaon, Near Ganesh Mandir, NH 37, Kamrup, Guwahati, Assam 781033, India	Institutional Ethics Committee, Excelcare Hospitals, (Unit of Asclepius Hospital and Healthcare Private Ltd.) Paschim Boragaon, Near Ganesh Mandir, NH 37, Kamrup, Guwahati, Assam 781033, India	Dr Manash P Baruah
		ECR/1230/Inst/AS/2019	

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12.	Department of Endocrinology, Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai - 400012, Maharashtra, India	Institutional Ethics Committee-I, New UG/PG Hostel, 20 Storey Hostel Building, Ground Floor, KEM Hospital Campus, Near Main boys Hostel, Dr. S. S. Rao Marg, Parel, Mumbai 400 012 Maharashtra India ECR/229/Inst/MH/2013/RR-19	Dr Anurag Ranjan Lila
13.	Gujarat Endocrine Centre, 2nd Floor, Silver Brook-B, Opp. Doctor House, Nr Parimal Crossing, Ahmedabad, Gujarat 380006, India	Sangini Hospital Ethics Committee, Sangini Hospital Santorini Square, B/H Abhishree Complex, Nr Jodhpur Cross Roads, Satellite Ahmedabad Ahmedabad Gujarat -380015 India ECR/147/Inst/GJ/2013/RR-19	Dr Parag Rajnikant Shah
