

1. Dr Mohammed Abubakar, Owaisi Hospital and Research Centre, DMRL X Road, Santhosh Nagar, Hyderabad - 500058
2. Dr Faraz Farishta, Medwin Hospital, Raghava Ratna Towers, Chirag Ali Lane, Nampally, Hyderabad 500001, Telangana.
3. Dr M A Shekar, Dept of Endocrinology, K.R. Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysore 570001, Karnataka.
4. Dr Abhay Mutha, Grant Medical Foundation, Ruby Hall Clinic, 40, Sassoon Road, Pune 411001, Maharashtra.
5. Dr Neeraj Manikath, Dept. of General Medicine, Govt. Medical College, Kozhikode 673008, Kerala.
6. Dr Shehla Sajid Shaikh, Prince Aly Khan Hospital, Aga Hall, Nesbit Road, Mazgaon, Mumbai 400 010
7. Dr Prabir Kumar Kundu, Dept of Endocrinology Nutrition and Metabolic Diseases Calcutta School of Tropical Medicines, 108 Chittaranjan Avenue, Kolkata.

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the Protocol No: NNS401-4243, Version 2.0 dated 30 Sep 2015, submitted to this Directorate.

Sir/Madam,

Reference: -Your letter no. NN/RA/SPTP/457, dt: 06-Jul-2015 on the subject mentioned above.

Subject: Permission for conducting a Phase IIIb clinical trial titled "A Trial Comparing Efficacy And Safety Of Insulin Degludec/Insulin Aspart Twice Daily And Biphasic Insulin Aspart Twice Daily In Subjects With Type 2 Diabetes Mellitus Before, During And After Ramadan." - regarding.

To,
M/s Novo Nordisk India Private Ltd,
Plot No. 32, 47 - 50, EPIP Area,
Whitefield, Bangalore,
Karnataka - 560 066.

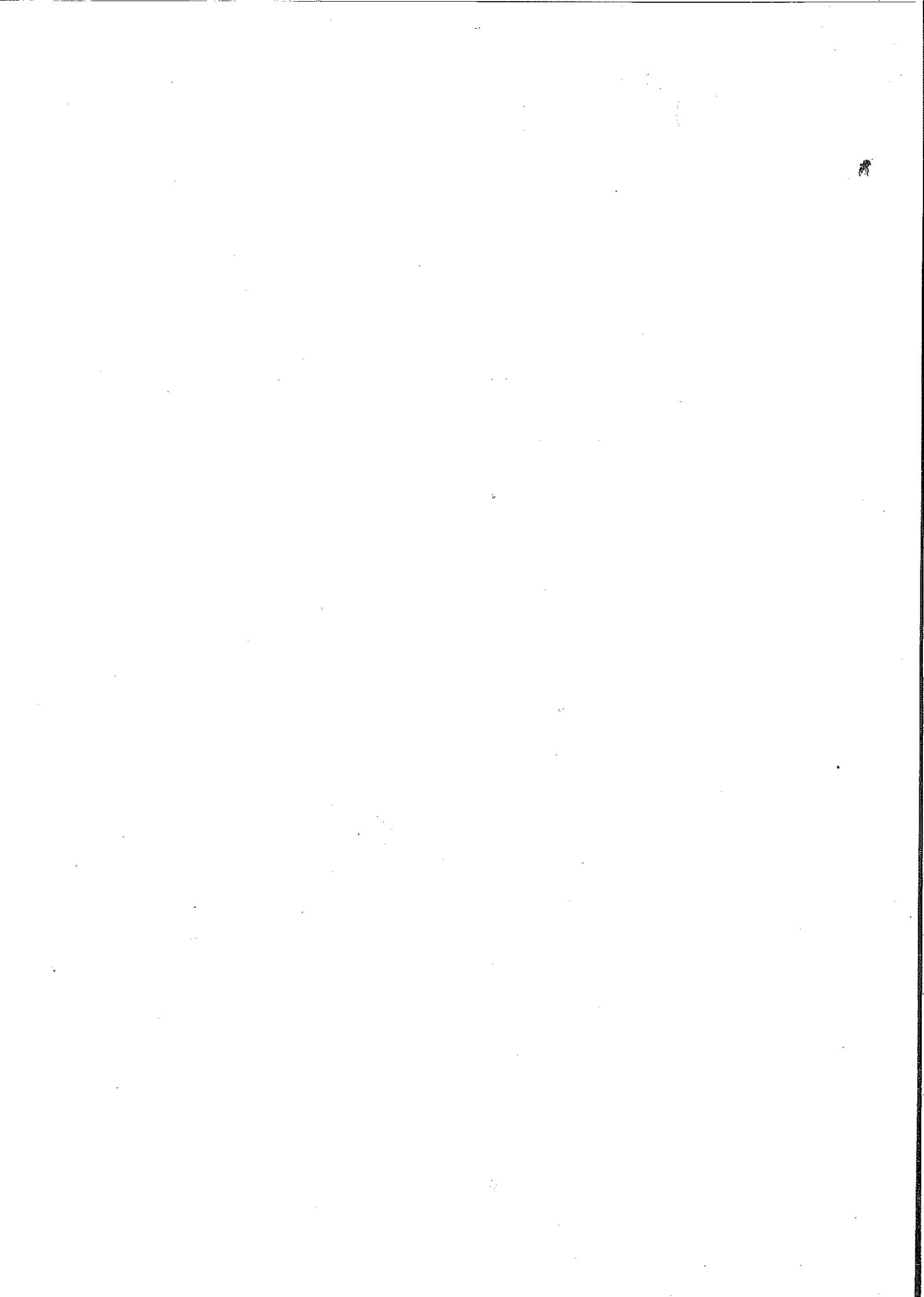
File No: CT/34/15 - DCG (I)

Date: 01-03-16

Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(Global Clinical Trial Division)
FDA Bhawan, Kotla Road, New Delhi-110002
Tel No: 01123236965, Fax: 01123236971
E-mail: dci@nic.in

GOVERNMENT OF INDIA

22407/10.07.2015



Directorate General of Health Services
Central Drugs Standard Control Organization
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FDA Bhawan, Kotla Road, New Delhi-110002
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To,

M/s Novo Nordisk India Private Ltd,
Plot No. 32, 47 - 50, EPIP Area,
Whitefield, Bangalore,
Karnataka - 560 066.

Subject: Permission for conducting a Phase IIb clinical trial titled "A Trial Comparing Efficacy And Safety Of Insulin Degludec/Insulin Aspart Twice Daily And Biphasic Insulin Aspart Twice Daily In Subjects With Type 2 Diabetes Mellitus Before, During And After Ramadan." - regarding.

Reference: -Your letter no. NN/RA/SPTP/457, dt: 06-Jul-2015 on the subject mentioned above.

Sir/Madam,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs & Cosmetics Rules under supervision of the following investigators and as per the Protocol No: NNS401-4243, Version 2.0 dated 30 Sep 2015, submitted to this Directorate.

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7. Dr Prabir Kumar Kundu, Dept of Endocrinology Nutrition and Metabolic

Diseases Calcutta School of Tropical Medicines, 108 Chittaranjan Avenue,

Kolkata.

Kindly note that the clinical trial permission is subject to the following conditions:

- a. The minimum gap between two injections of IMP should be 8hrs.
- b. Standard procedure for the management of hypoglycemia during Ramadan should be clearly mentioned in ICF as well as in study protocol.

c. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations;

d. Approval of the Ethics Committee shall be obtained before initiation of the study;

e. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study;

f. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority;

g. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y;

h. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority;

i. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations;

j. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

k. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

1. The sponsor shall ensure that the number of clinical trials an investigator can undertake should be commensurate with the nature of the trial, facility available with the Investigator etc. However, under no circumstances the number of trials should be more than three at a time.

m. The details of payment/honorarium/financial support/fees paid by the Sponsor to the Investigator(s) for conducting the study shall be made available to this directorate before initiation of each of the trial sites.

n. An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record. Provided that in case of clinical trial of anti-HIV and anti-Leptosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

o. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

Yours faithfully,

(Dr. V.G. Somani)
Joint Drugs Controller (India) &
Licensing Authority



