F. No. BIO/CT/18/000090
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi - 110002

To,

M/s Wockhardt Limited,
Research Centre, MIDC, D-4, MIDC, Chikalthana,
Aurangabad Maharashtra (India) - 431006

Subject: Permission for conducting a Phase 1 clinical trial titled "A Pilot Study To Compare Bioavailability Between Recombinant Human Isophane Insulin Injections Wockhardt's Wosulin® N and Humulin® N, In Healthy Male Subjects" as per Protocol No.: W-WOS(N)-103 V. No.03, dated 08-May-2019 under the D&C Act and Rules thereunder - regarding

Reference:- Your application no. BIO/Form44/FF/2018/12043 dated 07-Dec-2018 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting subject mentioned study under the provisions of Drugs and Cosmetics Rules 122-DA and 122-DAC, under the supervision of Principal Investigator mentioned below as per Protocol No.: W-WOS(N)-103 V. No.03, dated 08-May-2019 submitted to this Directorate.

Sr. No.	Name of Principal Investigator	Clinical Trial Site address	Name and Address of the Ethics Committee
1	Dr. Nilesh Lomte, MD (Medicine)	Clinical Pharmacokinetics & Biopharmaceutics Department, Wockhardt Limited, D-4, MIDC Area, Chikalthana, Aurangabad-431006, Maharashtra, India	Institutional Ethics Committee Dept. of Pharmacology, Govt. Medical College, Aurangabad-431001, Maharashtra, India EC Reg. No.: ECR/314/Inst/MH/2013/RR-16

Licensing Authority as defined in clause (b) of Rule 21, issue permission for conduct of clinical trial, subject to the following conditions further, namely:-

(a) Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y annexed to these rules, Good Clinical Practice Guidelines for conduct of clinical trials in India and other applicable regulations.

(b) Approval of the Ethics Committee shall be obtained before initiation of the study.

(c) Clinical trial shall be registered at Clinical Trials Registry of India before enrolling the first patient for the study.

(d) 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.

(e) Any report of serious adverse event occurring during clinical trial 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.

(f) In case of an injury or death during the clinical trial to the subject of the clinical trial 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.

(g) The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites shall be open to inspection by the officers 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 trials in India and other applicable regulations.

(h) The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites and the investigator shall allow officers authorized by the Central Drug 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 trials and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

(i) Submit complete report of clinical trials as per the approved protocol from the individual investigator duly signed by him along with his observations/remarks on the drug indicating the date of commencement and conclusion of the clinical trial at each center (in case the study is multicentric).

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

(k) 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.

(l) 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.

It is informed that all the amendments to Rule 122DAA, inclusion of Rule 122DAB, compensation matters etc. that are appended to the Drugs & Cosmetics Act & Rule, vide GSR 53 (E) dated 30.01.2013 and in Part X-A, after Rule 122DAB, Rule 122 DAC vide GSR 63 (E) dated 01.02.2013 are mandatory and binding.

Yours faithfully,

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
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Date: 2019.07.01 12:34:50 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (India)
Licensing Authority