



File No. BIO/CT/21/000086

Dated 11-Jan-2022

To,
M/s Wockhardt Limited,
Plot No. C-2, Wockhardt Towers Bandra Kurla Complex,
Bandra (East), Mumbai (India) – 400051

Subject: Application for grant of permission to conduct Phase IV clinical trial entitled –“A Prospective, Open-Label, Randomized, Parallel Group, Comparative, Multi-center, Phase IV Trial to Evaluate the Immunogenicity and Safety of Wockhardt’s Basal or Bolus human insulin (Wosulin R, Wosulin N and Wosulin 30/70) with Eli Lilly’s Basal or Bolus human insulin (Huminsulin R, Huminsulin N and Huminsulin 30/70) in Subjects with Diabetes Mellitus” as per Protocol No.: WOC/WOS/CT-37/14, Version No.: 02, Date 08 Jan 2021, Amendment No.: 01 Date: 10 Nov 2021- regarding

Ref.: Your Application No. BIO/CT04/FF/2021/26832 dated 15-Jul-2021

Sir,

With reference to your Application No.: BIO/CT04/FF/2021/26832 dated 15-Jul-2021, please find enclosed herewith the permission in Form CT-06 for conduct of subject Phase IV clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019.

The permission granted by the Central Licensing Authority to conduct clinical trial under this Chapter shall be subject to following conditions, namely:

- (I) The firm should submit an interim analysis after completion of six months study.
- (II) 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 Licensing Authority under rule 8;
- (III) 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;

- (IV) 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;
- (V) The Central Licensing 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;
- (VI) 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;

- (VII) 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;
- (VIII) Status of enrolment of the trial subjects shall be submitted to the Central Licensing Authority on quarterly basis or as appropriate as per the duration of treatment in accordance with the approved clinical trial protocol, whichever is earlier;
- (IX) Six monthly status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Central Licensing Authority electronically in the SUGAM portal;
- (X) In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licensing Authority within thirty working days of such termination;
- (XI) 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 Licensing 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;
- (XII) 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 Licensing Authority within thirty working days of the receipt of order issued by Central Licensing Authority in accordance with the provisions of the said Chapter;
- (XIII) 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 Licensing Authority within thirty working days of receipt of the order issued by the Central Licensing Authority in accordance with the provisions of the said Chapter;
- (XIV) The premises of the sponsor including his representatives and clinical trial sites, shall be open for inspection by officers of the Central Licensing Authority who may be accompanied by officers of the State Licensing Authority or outside experts as authorised by the Central Licensing 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;
- (XV) 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;
- (XVI) The Central Licensing 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;
- (XVII) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.

HEALTH, GOVERNMENT OF INDIA
Yours faithfully,

VENUGOPA
L G SOMANI

(Dr. V.G. Somani)

Drugs Controller General (India)

Digitally signed by VENUGOPA L G SOMANI
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CONTROLLER GENERAL (INDIA),
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FORM CT-06

(See rules 22, 25, 26, 29 and 30)

**PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG**

The Central Licencing Authority hereby permits M/s Wockhardt Limited, Plot No. C-2, Wockhardt Towers Bandra Kurla Complex, Bandra (East), Mumbai (India) – 400051 to conduct clinical trial of the new drug or investigational new drug study titled “A Prospective, Open-Label, Randomized, Parallel Group, Comparative, Multi-center, Phase IV Trial to Evaluate the Immunogenicity and Safety of Wockhardt’s Basal or Bolus human insulin (Wosulin R, Wosulin N and Wosulin 30/70) with Eli Lilly’s Basal or Bolus human insulin (Huminsulin R, Huminsulin N and Huminsulin 30/70) in Subjects with Diabetes Mellitus” as per protocol No.: WOC/WOS/CT-37/14, Version No.: 02, Date 08 Jan 2021, Amendment No.: 01 Date: 10 Nov 2021 in the below mentioned clinical trial sites.

2. Details of 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: 11-Jan-2022

**VENUGOPA
L G SOMANI**

Digitally signed by VENUGOPAL G SOMANI
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(Dr. V.G. Somani)
Drugs Controller General (India)
Central Licencing Authority

सत्यमेव जयते

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Isophane Insulin Injection IP	
Therapeutic class:	Antidiabetic	
Dosage form:	Solution for Injection	
Composition:	Name of Ingredients	Quantity per ml
	Insulin human(recombinant)	100IU*
	Disodium hydrogen phosphate anhydrous	3.78mg
	Glycerol	16.32mg
	Zinc oxide ^{\$}	0.025mg(Zinc)
	m-cresol	1.6mg
	Phenol	0.65mg
	Protamine sulphate	0.35mg
	Sodium hydroxide	q.s. to pH
	Hydrochloric acid	q.s. to pH
	Water for Injection	q.s to 1ml
*Overage of 1.25% of Insulin Human is added during formulation \$ The amount of Zinc oxide added to the formulation is dependent on the amount of zinc in the Human Insulin used. The target amount for Zinc in the formulation is 25µg per 100 IU Insulin		
Indications:	Diabetes Mellitus (Type 1 DM and Type 2 DM)	

Names of the new drug or investigational new drug:	Insulin Injection IP	
Therapeutic class:	Antidiabetic	
Dosage form:	Solution for Injection	
Composition:	Name of Ingredients	Quantity per ml
	Insulin human(recombinant)	100IU*
	Citric acid monohydrate	0.0021
	Glycerol	16.32mg
	Zinc oxide ^{\$}	0.025mg(Zinc)
	m-cresol	2.50mg
	Tri sodium citrate dehydrate	0.19mg
	Sodium hydroxide	q.s. to pH
	Hydrochloric acid	q.s. to pH
	Water for Injection	q.s to 1ml
	*Overage of 1.25% of Insulin Human is added during formulation \$ The amount of Zinc oxide added to the formulation is dependent on the amount of zinc in the Human Insulin used. The target amount for Zinc in the formulation is 25µg per 100 IU Insulin	
Indications:	Diabetes Mellitus (Type 1 DM and Type 2 DM)	

Names of the new drug or investigational new drug:	Biphasic Isophane Insulin Injection IP	
Therapeutic class:	Antidiabetic	
Dosage form:	Solution for Injection	
Composition:	Name of Ingredients	Quantity per ml
	Insulin human(recombinant)	100IU*
	Disodium hydrogen phosphate anhydrous	2.08mg
	Glycerol	16.32mg
	Zinc oxide [§]	0.025mg(Zinc)
	m-cresol	1.6mg
	Phenol	0.65mg
	Protamine sulphate	0.234mg
	Sodium hydroxide	q.s. to pH
	Hydrochloric acid	q.s. to pH
	Water for Injection	q.s to 1ml
*Overage of 1.25% of Insulin Human is added during formulation [§] The amount of Zinc oxide added to the formulation is dependent on the amount of zinc in the Human Insulin used. The target amount for Zinc in the formulation is 25µg per 100 IU Insulin		
Indications:	Diabetes Mellitus (Type 1 DM and Type 2 DM)	

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee Details	Name of Principal Investigator
1	Lifecare Hospital and Research Centre, 2748/2152, M.L.N. Enclave, 16th E Cross Road, 8th Main, D Block, Next to Union Bank, Sahakarnagar, Bengaluru – 560092	Life Care Hospital Intuitional Review Board. 2748/2152, M.L.N. Enclave, 16th E Cross Road, 8th Main, D Block, Next to Union Bank, Sahakarnagar, Bengaluru – 560092 EC Reg no: ECR/883/Inst/KA/2017/RR-20	Dr L Sreenivasa Murthy
2	BLK Super Specialty Hospital Pusa Road, Rajendra Place, New Delhi, Delhi 110005	Dr B L Kapur Memorial Hospital Ethics Committee, Dr B L Kapur Memorial Hospital Academic Affairs Research and continuing Education, Pusa Road, Rajendra Place, New Delhi, Delhi 110005 EC Reg no: ECR/3/BLK/Int/DL/2013/RR-19	Dr. Ajay Kumar Ajmani
3	Medstar Speciality Hospital, #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore-560092, Karnataka, India.	Medstar Speciality Hospital Ethics committee. Medstar Speciality Hospital, #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore- 560092, Karnataka, India. EC Reg. No.: ECR/1324/Inst/KA/2019	Dr Chikkalingaiah Siddegowda

4	Vishesh Diabetes Centre,# 423, 1st Floor, above Kanti Sweets, Aswath Naagr, Tanisandra Main Road, Bengaluru - 560077, Karnataka, India	Medstar Speciality Hospital Ethics committee,Medstar Speciality Hospital, #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore-560092 ,Karnataka,India. EC Reg no: ECR/1324/Inst/KA/2019	Dr Ambrish
5	Downtown Hospital LtdG S Road Dispur Guwahati Kamrup Metropolitan Assam - 781006 India	Ethics Committee,Downtown hospital Ltd,G S Road Dispur Guwahati Kamrup Metropolitan Assam - 781006 India EC Reg no:ECR/549/Inst/AS/2014/RR- 20	Dr. Rupam Das
6	Lifepoint Multispecialty Hospital 3rd Floor, Clinical Research Department, 145/1,Mumbai Bangalore Highway,Near Hotel Sayaji,Wakad,Pune- 411057,Maharashtra,India	LPR Ethics Committee Lifepoint Multispecialty Hospital, 145/1,Mumbai Bangalore Highway,Near Hotel Sayaji,Wakad,Pune-411057, Maharashtra,India EC Reg no:ECR/751/INST/MH/2015/RR- 18	Dr. Amol Dange

