File No. CT/18/22-DCG(I)

GOVERNMENT OF INDIA
CENTRAL DRUGS STANDARD CONTROL ORGANISATION (Headquarter)
(Directorate General of Health Services)
Ministry of Health & Family Welfare
FDA Bhavan, Kotla Road,
New Delhi – 110002
Phone No.: 91-11-23216367
Fax No.: 91-11-23236973
E-Mail : dci@nic.in

सत्यमेव जयते

File No. CT/22/000018

To,

M/s Labcorp Drug Development India Pvt. Ltd.,
Building no 1, Unit no 601,R aheja Mindspace Plot nos Gen/2/1D/E/F,
MIDCTTC Industrial Area, Shiravane Thane (India) – 400706.

Sir,

With reference to your application for change the name from Covance India Pharmaceuticals Services Pvt. Ltd. GCT/CT04/FF/2020/22166 (GCT/10/21) dated 20-01-2021 to Labcorp Drug Development India Pvt. Ltd. GCT/CT04/FF/2022/30626 (GCT/18/22) dated 16/02/2022, please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **EMPACT-MI: "A streamlined, multicentre, randomised, parallel group, double-blind placebo-controlled superiority trial to evaluate the effect of EMPAgliflozin on hospitalisation for heart failure and mortality in patients with aCuTe Myocardial Infarction" Protocol No.: 1245-0202 Version No. 1.0 dated 03-07-2020** 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 include equal number of academic/government medical institutions site in 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;

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 Licensing Authority and may be used for test or analysis of any drug for and on behalf of Central Licensing 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.

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,

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
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Date: 2022.05.19 14:22:37 +05'30'

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

File No. CT/18/22-DCG(I)

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 Labcorp Drug Development India Pvt. Ltd., Building no 1, Unit no 601, Raheja Mindspace Plot nos. Gen/2/1D/E/F, MIDCTTC Industrial Area, Shiravane Thane (India) - 400706** to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: 1245-0202 Version No. 1.0 dated 03-07-2020** 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 ________________

VENUGOPAL G SOMANI

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb2557 [illegible]58748 ee3113c, postalCode=110002, st=DELHI, serialNumber=[illegible]22525 ffca0705074b4997e6b2f4b5c8d81cf282ad eaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.05.19 14:22:45 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licensing 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	Jardiance
Therapeutic class:	Cardiovascular
Dosage form:	Tablets
Composition:	Empagliflozin = 10.0000 milligram (mg) U.S.P.,J.P. Active
Indications:	Heart failure and acute myocardial infarction

Annexure:

Details of clinical trial site:

Sr. No.	Names and address of clinical trial site	Ethics committee details	Name of investigator
1.	Room No-15, 1* Floor, Batra Heart Centre, Batra Hospital and Medical Research Centre, 1 Tughlakabad Institutional Area, Mehrauli- Badarpur Road, New Delhi-110062	Scientific Research and Ethical Review Committee, Department of Laboratory Medicine, Batra Hospital & Medical Research Centre,1, Tughlakabad Institutional Area, Mehrauli - Badarpur, Road, New Delhi-110062, India ECR/295/Inst/DL/2013/RR-19	Dr. Upendra Kaul
2.	Eternal Heart Care Centre and Research Institute Pvt. Ltd., 3 A Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan, India	Eternal Heart Care Centre and Research Institute - Institutional Ethics Committee, 3 A Jagatpura Road, Near Jawahar Circle, Jaipur-302017, Rajasthan, India ECR/615/Inst/RJ/2014/RR-20	Dr. Jugal Bihari Gupta
3.	Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bannerghatta Road, Jayanagar 9th Block, Bangalore-560069	Sri Jayadeva Ethics Committee, Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bannerghatta Road, Jayanagar 9th Block, Bangalore-560069 ECR/423/Inst/KA/2013/RR-19	Dr. C N Manjunath
4.	Max Super Speciality Hospital, Saket (East Block) (A Unit of Devki Devi Foundation) 2, Press Enclave Road, Saket, New Delhi-110017, India	Institutional Ethics Committee, Max Super Speciality Hospital, Saket (East Block) (A Unit of Devki Devi Foundation) Service Floor, Office of Ethics Committee, 2, Press Enclave Road, Saket, New Delhi-110017, India ECR/110/Inst/DL/2013/RR-19	Dr. V. K Chopra
5.	Lisie Hospital, North Kaloor, Kochi, Kerala-682018	Institutional Ethics Committee, Lisie Hospital, North Kaloor, Kochi, Kerala-682018 ECR/40/Inst/KL/2013/RR-20	Dr. Jabir Abdullakutty
6.	Kamalnayan Bajaj Hospital, Gut No. 43, Satara Parisar, Beed Bypass Road, Aurangabad-431010, MH, India	Ethics Committee Kamalnayan Bajaj Hospital, Gut No. 43, Satara Parisar, Beed Bypass Road, Aurangabad-431010, MH, India ECR/444/Inst/MH/2013/RR-20	Dr. Ajit Raghunath Bhagwat

7.	King Edward Memorial VII Hospital & Seth Gordhandas Sunderdas Medical College 4th Floor, CVTC Building, Department of Cardiology, Acharya Donde Marg, Parel 400012 Mumbai, Maharashtra- India	Institutional Ethics Committee (IEC-I) New UGIPG Hostel, 20th Storey Hostel Building, Ground floor, KEM Hospital Campus, Near main Boys Hostel, Or S.S. Rao's Marg, Gate No.07, Parel, Mumbai 400012, Maharashtra, India ECR/229/Inst/MH/2013/RR-19	Dr. Prafulla Kerkar
8.	KLES Dr. Prabhakar Kore Hospital and MRC, SMO, Sharawati Ward, Second Floor, Nehru Nagar, Belagavi-590010, Karnataka, India	Institutional Ethics Committee, KLE University, KLE University, Dr. P.K. Hospital and MRC, Nehru Nagar, Belagavi-590010, Karnataka, India ECR/211/Inst/Ka/2013/RR-19	Dr. Kothiwale Veerappa Annasaheb
9.	Narayana Institute of Cardiac Sciences-Unit of Narayana Health, #258/A, Bommasandra Industrial Area, Hosur Road, Anekal Taluk, Bangalore-560099, Karnataka, India	Narayana Health Medical Ethics Committee, #258/A, Bommasandra Industrial Area, Hosur Road, Anekal Taluk, Bangalore-560099, Karnataka, India ECR/390/Inst/KA/2013/RR-19	Dr. Srikanth K.V
10.	Institute of Cardiovascular Diseases, The Madras Medical Mission, 4-A, Dr. J.J. Ayalalithaa Nagar, Mogappair, Chennai-600037, Tamil Nadu, India	Institutional Ethics Committee, The Madras Medical Mission, 4-A, Dr.J.Jayalalitha Nagar, Mogappair, Chennai-600037 ECR/140/Inst/TN/2013/RR-20	Dr. Mullasari Ajit Sankardas
11.	Sahyadri Super Specilality Hospital, Survey No. 185A, Shastri Nagar, Near MSEB Office, Yerwada, Nagar Road, Pune-411006, Maharashtra, India Clinical Research Unit (Unit of Sahyadri Super Speciality Hospital, Nagar Road) Unit No. 202 & 206, 2nd Floor, Hermes Center Premises Society Ltd., Survey No. 185 & 189, Shastri Nagar, Yerwada, Nagar Road, Pune-411006, Maharashtra, India	Sahyadri Hospitals Ltd Ethics Committee, Sahyadri Clinical Research and Development Center, 33/34b , Makarand Bhave Path, Karve Road, Pune-411004, Maharashtra ECR/493/Inst/MH/2013/RR-19	Dr. Govind Kulkarni

12.	Mahatma Gandhi Mission Medical College & Hospital, N-6, CIDCO, Aurangabad-431003, MH, India.	Mahatma Gandhi Mission Ethics Committee for Research on Human Subjects, Pharmacology Department, Third Floor, N-6, CIDCO, Aurangabad-431003, MH India ECR/581/Inst/MH/2014/RR-20	Dr. Prashant Prabhakar Udgire
13.	Sir Ganga Ram Hospital SGRI Marg. Rajinder Nagar, New Delhi 110060. India	Sir Ganga Ram Hospital Ethies Committee, Room 1496. 4h Floor. Old Building Old Rajinder Nagar. New Delhi 110060. India ECR/20/Inst/DL/2013/RR-19	Dr. Ashwani Mehta
14.	Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai-400022, Maharashtra, India	Institutional Ethics Committee – Human Research Room no 17, Second floor, college building, Lokmanya Tilak Municipal Medical College & General Hospital, Sion, Mumbai-400022 ECR/266/Lokmanya/Inst/MH/2013	Dr. Mahajan Ajaykumar Umakant
15.	Government Medical College and Super Specialty Hospital, Tukdoji Square, Nagpur - 440009, Maharashtra, India	Institutional Ethics Committee, GMC, Nagpur Government Medical College & Hospital, Medical Square Hanuman Nagar, Nagpur Maharashtra- 440003 India ECR/43/Inst/MH/2013/RR-19	Dr. Sunil Nilkanthrao Washimkar
16.	GB Pant Institute of Post Graduate Medical Education and Research 1, Jawaharlal Nehru Marg, 64 Khamba, Raj Ghat, New Delhi, Delhi 110002	Institutional Ethics Committee. 3 rd floor, Room no. 306A, Maulana Azad Medical College, Bahadur Shah Zafar Marg, New Delhi -110002 ECR/329/Inst/DL/2013/RR-19	Dr. Girish MP
17.	Department of Cardiology Sanjay Gandhi Post Graduate Institute of Medical Sciences. Rae Bareli road, Lucknow, UP- 226014	Institutional Ethics Committee - Sanjay Gandhi post Graduate Institute of Medical Sciences Rae Bareli road, Lucknow, UP-226014 ECR/16/Inst/UP/2013/RR-20	Dr. Sudeep Kumar

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