



सत्यमेव जयते

**GOVERNMENT OF INDIA**  
CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION(Headquarter)(  
Directorate General of Health Services)  
Ministry of Health & Family Welfare  
FDABhavan  
ITO, Kotla Road New  
Delhi - 110002 (Delhi) Phone No.:  
91-11-23216367  
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**File No. CT/20/000069**

To,

M/s. George Clinical India Pvt Ltd,  
Plot No. 5, Prestige Khoday Towers, 12th Floor,  
Raj Bhavan Road, Karnataka (India) - 560001

Sir,

With reference to your application No GCT/CT04/FF/2020/20643 (GCT/67/20) dated 17-07-2020 please find enclosed herewith the permission in Form CT-06 for conduct of clinical trial titled, **“An International, Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study Evaluating the Efficacy and Safety of Dapagliflozin in Respiratory Failure in Patients with COVID-19”, Protocol number D1690C00081 Protocol Version 3.0 dated 20/05/2020** 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:-

- (i) **Patient with SpO2 more than 94% or on room air will be excluded from the study.**
- (ii) **All cost of lab Investigation, Hospitalization and therapy for the standard management of patients under clinical trial should be borne by the Sponsor.**
- (iii) 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 rule8;
- (iv) 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 rule7:  
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;
- (v) 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;
- (vi) 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;
- (vii) 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;

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- (viii) 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;
- (ix) 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;
- (x) 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;
- (xi) 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;
- (xii) 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;
- (xiii) 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;
- (xiv) 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;
- (xv) 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;
- (xvi) 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;
- (xvii) 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;
- (xviii) 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;
- (xix) the sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xx) 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

**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. George Clinical India Pvt Ltd, Plot No. 5, Prestige Khoday Towers, 12th Floor Raj Bhavan Road Bengaluru (India) – 560001** to conduct clinical trial of the new drug or investigational new drug as per **Protocol number D1690C00081 Protocol Version 3.0 dated 20/05/2020** 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 \_\_\_\_\_

(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:

<b>Names of the new drug or investigational new drug</b>	Dapagliflozin
<b>Therapeutic class:</b>	sodium glucose cotransporter 2 or SGLT2 inhibitors
<b>Dosage form:</b>	Tablets

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<b>Composition:</b>	Dapagliflozin >95.0000 % In House Specification Active
<b>Indications:</b>	Respiratory Failure in Patients with COVID-19

**Annexure:**

Details of clinical trial site

<b>Names and address of clinical trial site</b>	<b>Ethics committee details</b>	<b>Name of investigator</b>
Medanta-The Medicity, Ch. Bakhtawar Singh, Chowk, Sector 38, Gurugram, Haryana- 122001	Medanta Institutional Ethics Committee, Medanta-The Medicity, Sector 38, Gurugram, Haryana-122001 India  ECR/282/Inst/HR/2013/RR-20	Dr. Sanjay Mittal
Dept. of Endocrinology & Metabolism, AIIMS, Ansari Nagar, New Delhi - 110029	Institute Ethics Committee, Room No. 102, 1 <sup>st</sup> Floor, Old O.T. Block, AIIMS, Ansari Nagar, New Delhi -110029  ECR/538/Inst/DL/2014/RR-17	Dr. Nikhil Tandon
Max Smart Super Specialty Hospital (A Unit of Gujarmal Modi Hospital & Research Centre for Medical Sciences), Mandir Marg, Press Enclave Road, Saket, New Delhi-110017	Max Healthcare Ethics Committee, Ground Floor, Office of Ethics Committee, West Block, Near MS Office, Max Sup Specialty Hospital Saket 1, Press Enclave Road Saket, New Delhi-110017  ECR/118/Inst/DL/2013/RR-19	Dr. Namrita Singh
Max Super Specialty Hospital Saket (East Block), (A Unit of Devki Devi Foundation) 2, Press Enclave Road, New Delhi-110017, India	Institutional Ethics Committee, Service Floor, Office of Ethics Committee, East Block, Next to Conference Room, Max Super Specialty Hospital Saket (A Unit of Devki Devi Foundation) 2, Press Enclave Road, New Delhi-110017, India  ECR/110/Inst/DL/2013/RR-19	Dr. R. S. Mishra
Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana, Punjab- 141001	Drug Trial Ethics Committee, Basement Hero DMC Heart Unit, Dayanand Medical College & Hospital, Tagore Nagar, Ludhiana-141001, Punjab	Dr. Rajesh Mahajan

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	ECR/101/Inst/PB/2013/RR-16	
Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, India	Ethics Committee, Sir Ganga Ram Hospital, SGRH Marg, Rajinder Nagar, New Delhi-110060, India  ECR/20/Inst/DL/2013/RR-19	Dr. Jitendra Pal Singh Sawhney
VMMC & Safdarjung Hospital, New Delhi-110029	Institutional Ethics Committee, VMMC & Safdarjung Hospital, Room No. 505 & 506, 5 <sup>th</sup> Floor, College Building, VMMC & Safdarjung Hospital, New Delhi-110029  ECR/593/Inst/DL/2014/RR-17	Dr. Sandeep Bansal
Sanjivani Superspeciality Hospital Pvt. Ltd., 1, Uday Park Society, Nr. Sunrise Park, Vastrapur, Ahmedabad-380015, Gujarat, India	Sanjivani Hospital Ethics Committee, Sanjivani Super Speciality Hospital 1, Uday Park Society, Near Sunrise Park, Vastrapur, Ahmedabad-380015, Gujarat, India  ECR183/Inst/Ahm/2013/RR-19	Dr. Kamal Harishchandra Sharma
AMRI Hospitals Dhakuria, P4 & 5 CIT Scheme LXXII Block- A Gariahat Road, Kolkata-700029	AMRI Hospitals Ethics Committee, P 4 & 5 CIT Scheme, Block-A Gariahat Road, Kolkata-700029, Kolkata West Bengal-700029, India  ECR/871/Inst/WB/2016/RR-19	Dr. Sujoy Ghosh
Pushpawati Singhania Research Institute, Press Enclave Marg, Sheikh Sarai II, New Delhi-110017, India	Institutional Ethics Committee , Pushpawati Singhania Research Institute, Press Enclave Marg, Sheikh Sarai II, New Delhi-110017, India  ECR/87/Inst/DL/2013/RR-19	Dr. Vinayak Agrawal