

ND/CT04/FF/2020/21372

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F. No. ND/CT/20/000074
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:

To

M/s Hetero Labs Limited,
7-2- A2, Sanath Nagar, Hyderabad,
Telangana- 500018

11 7 AUG 2021

Subject:- Permission to conduct study post approval for restricted use under emergency situation for Remdesivir Injection evaluating the Efficacy, Safety and Tolerability of Remdesivir Injection in Participants with Severe Coronavirus Disease (COVID-19)(HEREMICOV STUDY) vide Protocol no. HCR/IV/HEREMICOV/05/2020; Protocol Version: V1.0; 25.05.2020 –**Reg.**

Sir,

With reference to your application no. ND/CT21/FF/2020/21372 dated 28.08.2020; please find enclosed herewith the permission in **Form CT-06, No. CT/ND/77/2020** to conduct subject mentioned study post approval for restricted use under emergency situation under the provisions of **New Drugs and Clinical Trial Rules, 2019** granted based on evaluation in consultation with Subject Expert Committee (SEC).

This permission is subject to the conditions, as mentioned below.

Yours faithfully


(Dr. V. G. Sormani)
Central Licensing Authority

Condition of permission

- (i) 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;
- (ii) 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;

- (iii) 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;
- (iv) 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;
- (v) 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;
- (vi) 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;
- (vii) 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;
- (viii) 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;
- (ix) 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;
- (x) 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 of the New Drugs and Clinical Trials Rules, 2019;
- (xi) In case of injury during clinical trial to the subject of such trial, complete medical management and compensation shall be provided in accordance with the Chapter VI of the said Rules 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;

- (xii) 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 the 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;
- (xiii) 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;
- (xiv) 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;
- (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 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;
- (xvii) The sponsor and the investigator shall maintain the data integrity of the data generated during clinical trial.
- (xviii) Informed Consent Documents (ICD) viz. Patient Information Sheet (PIS) and Informed Consent Form (ICF) complete in all respect & must be got approved from the respective Ethics committee and submitted to CDSCO before enrolling first subject at the respective site.
- (xix) **In the title of the study the words “moderate to severe” should be mentioned instead of “severe”.**
- (xx) **28 days Mortality should be an additional primary end point.**
- (xxi) **Viral clearance at 7, 14 days or at hospital discharge should be an additional secondary end point.**
- (xxii) **The hospital discharge and 2-point decrease in ordinal scale should be deleted from secondary endpoint as these are already covered in primary endpoint.**
- (xxiii) **Analysis plan should include comparison of the data from the study with the literature data.**
- (xxiv) **“Phase IV Clinical trial” should be replaced with “study post approval for restricted use under emergency situation”.**
- (xxv) **Accordingly, revised protocol should be submitted to CDSCO.**

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 Licensing Authority hereby permits M/s Hetero Labs Limited, 7-2- A2, Sanath Nagar, Hyderabad, Telangana- 500018 Tel : +91 40 23704923/24/25, Fax : 0091-40-23704035, 23813359, e-mail: contact@heterodrugs.com to conduct clinical trial of the investigational new drug as per **Protocol No. HCR/IV/HEREMICOV/05/2020 V1.0 dt 25.05.2020** in the below mentioned clinical trials sites.

2. Details of new drug or investigational new drug and clinical trial site:-

Names of the new drug or investigational new drug:	1. Remdesivir for Injection 100mg/ vial 2. Remdesivir Injection 100mg/20ml
Therapeutic class:	Antiviral
Dosage form:	1. Lyophilized powder for injection for IV infusion; 2. Liquid Injection.
Composition:	1. Each Lyophilized vial contains- Remdesivir100mg 2. Each vial contains: Remdesivir 100 mg/ 20 ml
Indications:	For treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalized with severe disease.

Details of clinical trial sites-

Sr. No.	Name of Principal Investigator & Trial Sites	Ethics Committee Name/ Registration Number
1.	Dr. Sunil Naik, Associate Professor MBBS, MD,(Gen. Medicine) Government Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam – 532001, Andhra Pradesh, India.	Institutional Ethics Committee, Government Medical College & Govt. General Hospital, Srikakulam- 532001 Andhra Pradesh, India ECR/492/Inst/AP/2013/RR-20
2.	Dr. B. Nagaraju Consultant Pulmonologist MBBS. M.D(Respiratory Medicine) Site Name: St. Theresa's Hospital Sanathnagar, Hyderabad- 500018,Telangana, India	Ethics Committee, St. Theresa's Hospital Sanathnagar. Hyderabad-500018, Telangana state, India. ECR/230/Inst/AP/2013/RR-19

3.	Dr. Keyur Madan Brahme, Assistant Professor MBBS, M.D.(Medicine) Sir Sayajirao General Hospital, Medical College- Baroda, Jail Road (Indira Avenue), Vadodara- 390001	Institutional Ethics Committee for Human Research, Medical College & S.S.G Hospital, Baroda, Vadodara-390001, Gujarat, India ECR/85/Inst/GJ/2013/RR-19
4.	Dr. Pugazhenthan Thangaraju, Assistant Professor, MBBS, MD, DNB, MNAMS(Pharmacology) All India Institute of Medical Science(AIIMS) G.E Road Tatibandh Raipur, Chhattisgarh- 492099	Institutional Ethics Committee, AIIMS Raipur Room No-2103, 2 nd Floor, Medical College Complex, Gate no-5, AIIMS, Raipur-492099 (C.G) India ECR/714/Inst/CT/2015/RR-18
5.	Dr. Sanjiv Maheshwari, Additional Principal, MD,(Gen. Medicine) Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer- 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer- 305001, Rajasthan, India ECR/1156/Inst/RJ/2018
6.	Dr. Kaushik Basu, Assistant Professor, MBBS, M.D. (Medicine), Medical College and Hospital , 88 College Street, Kolkata 700073, West Bengal	Institutional Ethics Committee for Human Research Medical College and Hospital 88 College Street, Kolkata 700073, West Bengal ECR/287/Inst/WB/2013/RR-19

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.

V.G.S.

(Dr. V. G. Soman)

Central Licensing Authority

Drugs Controller General of India
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002

New Delhi

Date:

17 AUG 2021