

Application no.  
ND/CT04/FF/20/21062

F. No. ND/CT/20/000066  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(New Drugs Division)

MS  
Tele No.011-23236965  
Fax.No.011-23236973

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

14 OCT 2020

To

M/s IDRS LABS PVT. LTD.,  
235 H, Phase 3, Bommasandra Industrial Area,  
Hosur road, Bangalore -560099

Subject: -Permission for conduct of "A phase-II, multi-centre, randomized, open label, two arm, controlled trial of sodium-copper-chlorophyllin given along with treatment of physician's choice versus treatment of physician's choice in asymptomatic or mildly symptomatic patients with SARS-CoV-2 Infection (Covid-19)"- Reg.

Sir,

With reference to your application ND/CT04/FF/2020/21062 dated 12-08-2020, please find enclosed herewith the permission in Form CT-06, No. CT/ND/112/2020 to conduct the subject mentioned clinical trial under the provisions of New Drugs and Clinical Trial Rules, 2019 granted based on evaluation in consultation with Subject Expert Committee as part of accelerated approval process in light of Covid-19 outbreak.

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

Yours faithfully

V.G.S.

(Dr. V. G. Somani)  
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 authorized 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 utilized 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;
- (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) **Viral clearance and clinical progression based on WHO ordinal scale should be primary end point.**
- (xx) **Cytokine assessment and all-cause modality should be secondary end point along with safety assessment etc.**
- (xxi) **The results of the Phase II Clinical Trial should be submitted CDSCO for review and consideration.**
- (xxii) **Undertaking of the investigator should be submitted before initiation of the clinical trial.**







**FORM CT-06**

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

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

Number of the permission and date of issue CT/ND/112/2020 dated 14 OCT 2020

1. The Central Licensing Authority hereby permits **M/s IDRS LABS PVT. LTD., 235 H, Phase 3, Bommasandra Industrial Area, Hosur road, Bangalore -560099** to conduct clinical trial of the new drug as per protocol no. **20-VIN-0270, Version -02, 25-09-2020** in the below mentioned clinical trials sites.
2. Details of new drug or investigational new drug and clinical trial sites: -

Names of the new drug or investigational new drug:	Sodium Copper Chlorophyllin
Therapeutic class:	Antiviral
Dosage form:	Tablet
Composition:	Each Tablets Contains Sodium Copper Chlorophyllin .....750mg.
Indications	For the treatment of asymptomatic or mildly symptomatic patients of SARS CoV-2 infection (Covid-19).

Details of clinical trial site			
Sl No.	Name and Designation	Address of Site	Name of Ethics Committee and address with Ethics Committee registration No
01	Dr. Jayanthi CR	Bangalore Medical college and Research Institute Ethics committee of Bangalore Medical College and Research Institute 1 <sup>st</sup> Floor, Bangalore Medical college and Research Institute K.R Road, Fort, Bangalore Karnataka-560002	Institutional Ethics committee, Bangalore Medical college and Research Institute Fort, K R Road Fort Bangalore-560002 EC Reg. No.: ECR/302/Inst/KA/2013/RR-20
02	Dr. Keyur Brahme	Medical college and SSG hospital, Dr. Shoyeb Sheikh, member Secretary, Institutional ethics committee on human research department of paediatrics,	Institutional Human Ethics Committee is GMERS, Medical College and General Hospital, Gotri, Vadodara - 390021, Gujarat, India EC Reg. No.-



		ward 17, first floor Vadodara Gujarat-390001	ECR/85/Inst/GJ/2013/RR-19
03	Dr. Shubhangi Deshpande	GMERS Medical College and General Hospital, Dr. Anand Patel, Institutional Human Ethics Committee Gotri Gujarat-390021	Institutional Human Ethics Committee GMERS, Medical College and General Hospital, Gotri, Vadodara - 390021, Gujarat, India EC Reg No.: ECR/28/Inst/GJ/2013/RR-19
04	Dr. Manish B Patel	NHLIEC, Smt NHL Municipal Medical college, VS Hospital Campus, Dr. Falguni Majmudar, Institutional Ethics Committee Ahmedabad Gujarat-380006	Institutional Ethics Committee, Smt. NHL, Municipal Medical College, Ellisbridge, Ahmadabad-380006, Gujarat, India EC. Reg. No. ECR/245/Inst/GJ/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.

New Delhi

Date: .....

  
**(Dr. V. G. Somani)**  
**Central Licensing Authority**  
**Stamp**  
**Dr. V. G. SOMANI**  
 Drugs Controller General (India)  
 Dte. General of Health Services  
 Ministry of Health and Family Welfare  
 FDA, Bhawan, Kotla Road, I.T.O.  
 New Delhi-110002

