

File No: BIO/CT/20/000182
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

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 Genova Biopharmaceuticals Limited, Emcure House, T-184, MIDC, Bhosari, Pune, Maharashtra, – 411 026, Telephone No.: 020-39821300, Fax: 020-39821300, E-Mail: maheshwari.mishra@emcure.co.in to conduct clinical trial of the new drug or investigational new drug as per Protocol no. GBL/HGCO19/2020/01, Version 1.0 dated 11.11.2020 in the below mentioned clinical trial sites.

CT No.: CT- 02/2021

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.

Date: 25-01-2021
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	mRNA Vaccine for Injection(COVID-19)	
Therapeutic class:	Vaccine	
Dosage form:	Solution for Injection for Intramuscular route of administration	
Composition:	Each 0.5 ml filled vial contains	
	Name of the ingredient	Quantity
	m-RNA	25 mcg
	DOTAP	0.75 mg
	Iron Oxide Nanoparticles	0.005 mg
	Squalene	0.94 mg
	Sorbitan Monostearate	0.93 mg
	Polysorbate 80 Ph. Eur./USPNF	0.93 mg
	Sucrose IP	50 mg
	Citric Acid Monohydrate IP	1.05 mg
Water for Injection IP/USP	q.s. to 0.5 ml	
Indications:	For prevention of COVID-19.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KEM Hospital Research Centre, , KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, Sardar Moodliar Road, Rasta Peth, Maharashtra, India Pune Maharashtra - 411011	KEY Hospital Research Centre Ethics Committee KEM Hospital Ressearch centre TDH BUILDING Ras1a peth IIIRD FLOOR. 303 Pune Pune Maharashtra - 411011 India ECRJ212J1nstlMHJ20131RR-19	Dr Pradeep Dcosta
2	Rajashree Chhatrapati Shahu maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Kolhapur, Dasara Chowk, Town Hall, Bhausingji road, kolhapur, maharashtra - 416 002	Institutional Ethics Committee, RCSMGMC and CPR Hospital , Kolhapur, Building No. 2, Quarter No 3, Room No. 7 Dassara Chowk Kolhapur Kolhapur Maharashtra - 416007 India ECR/703/Inst/MH/2015/RR-20	Dr Vijaykumar B Barge

In addition to point 3, the permission is subject to following condition(s):

1. The phase I/II clinical trial should be conducted as per protocol no. GBL/HGCO19/2020/01 Version 1.0 dated 11.11.2020 subject to the conditions as mentioned under this permission.
2. The permission is subject to RCGM Clearance.
3. Firm is required to submit the physical/biological characteristics, specification, dose & dosage form including storage temperature etc., of the HGC019 vaccine manufactured by

M/s Genova shall be same as that of HDT 301 vaccine developed by M/s HDT, Seattle, USA".

4. Firm is required to submit interim results of Phase I clinical trial before proceeding to Phase II clinical trial.
5. DSMB should be constituted to evaluate safety data.
6. Firm should submit ongoing stability (real time and accelerated) data of drug substance and drug product and ensure the stability of clinical trial batches to be used in proposed phase I/II clinical trial.
7. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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