

File No: BIO/CT/21/000105
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 Gennova Biopharmaceuticals Limited ,T-184 emcure house bhosari MIDC pune pune (India) - 411026 Telephone No.: 020-39821300 FAX: 020-39821300 E-Mail : sachin.gundecha@gennova.co.in to conduct clinical trial of the new drug or investigational new drug as per protocol no. HGCO19 (COVID-19 vaccine), Version 1.1 Dated 21 Aug 2021 in the below mentioned clinical trial sites.

CT No.: CT- 29/2021

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: 22-AUG-2021
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	HGCO19 Lyophilized mRNA Vaccine for Injection (COVID-19)	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized powder for Injection by Intramuscular route	
Composition:	Each 5 dose vial Contains:	
	Ingredients	Quantity
	m-RNA	50 mcg
	DOTAP	1.5 mg
	Squalene	1.88 mg
	Sorbitan Monostearate	1.86mg
	Polysorbate 80 Ph.Eur.	1.86 mg
	Sucrose IP	250 mg
	Citric acid monohydrate IP	5.25 mg
Indications:	Sterile Water for Injection IP (For reconstitution)	
	For active immunization against SARS-CoV-2 (COVID-19) in adult aged 18 years.	

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, Sardar Moodliar Road, Rasta Peth, Maharashtra, India Pune Maharashtra - 411011	KEM Hospital Research Centre, , TDH BUILDING Rasta peth III RD FILOOR. 303 Pune Maharashtra - 411011 India ECRJ212J1nstIMHJ20131RR-19	Dr Pradeep Dcosta
2	Rajashree Chhatrapati Shahu maharaj Govt. Medical College and Chhatrapati Pramila Raje General Hospital, Kolhapur, Dasara Chowk, Town Hall, Bhausingj 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
3	Dr D Y Patil Hospital, Pimpri, Pune	Ethics Committee –Dr D Y Patil Hospital, Dr D Y Patil Vidyapeeth, Pimpri, Pune ECR/361/Inst/MH/2013/RR-19	Dr Prakash Shende
4	The INCLIN Trust, OKHLA Industrial Area, Phase I, New Delhi	INCLIN independent Ethics Committee , F-1/5, OKHLA Industrial Area, Phase I, New Delhi ECR/109/Indt/DL/2014/RR-20	Dr Abhishek Agarwal
5	JSS Hospital, Mysore, Sri Shivarathreeshwara Nagar, Mysore	Institutional Ethics Committee JSS Medical College Sri Shivarathreeshwara Nagar, Mysore ECR/387/Inst/KA/2013/RR-19	Dr. Subhash Chandra B J
6	Noble Hospital, Pune,	Institutional Ethics Committee, Noble Annex, 153 A,	Dr S K Raut

		Magarpatta City Road, Hadapsar ECR/259/Inst/MH/2013/RR-19	
7	Sahyadri Hospital, Deccan, Pune Maharashtra	Sahyadri Hospital Ethics Committee, 33/34B, Makarand Bhave Path, Karve Road, Pune. ECR/493/Inst/MH/2013/RR-19	Dr Atul Joshi
8	DHS Hospital, Ahmedabad.	Sangini Hospital Ethics Committee, Santorini Square, B/H Abhishree Complex, Ahmedabad. ECR/147/Inst/GJ/2013/RR-19	Dr Smit Shah
9	Health Point Hospital, Kolkata.	Health Point Hospital Ethics Committee, 21 Prannath Pandit Street, Kolkata. ECR/284/Inst/WB/2013/RR-19	Dr Gouranga Sarkar
10	Hamdard Institute of Medical Sciences & Research, New Delhi	Jamia Hamdard Institutional Ethics Committee, Jamia Hamdard Nagar, New Delhi. ECR/48/Inst/DL/2013/RR-19	Dr. Sunil Kohli
11	Government Medical College (GMC), Nagpur.	Institutional Ethics Committee, GMC, GMC, Medical Square, Hanuman Nagar, Nagpur. ECR/43/Inst/MH/2013/RR-19	Dr. Gosavi Rajesh Vithal
12	ICMR NICED, Kolkata	Institutional Ethics Committee ICMR-NICED, P-33, CIT Road, Scheme Beliaghata, Kolkata, ECR/416/Inst/WB/2013/RR-20	Dr Shanta Dutta

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

- I. The Phase II/III comparator clinical trial should be conducted as per protocol titled "A Prospective, Multicentre, Randomized, Active-controlled, Observer-blind, Phase II study seamlessly followed by a Phase III study to evaluate the Safety, Tolerability and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy subjects." vide protocol no. GBL/HGCO19/2021/01 Version 1.1 Dated 21 Aug 2021.
- II. The firm is required to comply & submit following data/documents:
 - a. Copy of the Insurance Certificate.
 - b. Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.
 - c. IMP label as per requirements of ND& CT Rules for clinical trial sites.
- III. DSMB should be constituted for review of the safety data of the clinical trial.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Date: 22-AUG-2021
Place: New Delhi

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