File No: BIO/CT/20/000085

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 Cadila Healthcare Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213 Telephone No.: 7926868100 FAX: 7926862362 E-mail: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: NCOV 1002, Version No.: 01 Date: 27 Jun 2020** in the below mentioned clinical trial sites.

CT No.: CT- 15/2020

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: 02.07.2020

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2020.07.02 21:29:56 +05'30'

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

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

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Novel Corona Virus-2019-nCov vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for injection intradermally	
Composition:	Each 0.5 ml contains	
	Active ingredient	**Quantity**
	DNA plasmid construct with spike protein gene region from SARS-CoV-2 virus (Produced in *E. coli*)	5 mg
Indications:	Prevention of Corona Virus Disease -2019 in healthy subjects	

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
Phase I			
1	Zydus Research Centre,Survey No. 396/403, Sarkhej-Bavla National Highway No.8A Moraiya, Ahmedabad-382213	Zydus Research Centre,Survey No. 396/403, Sarkhej-Bavla National Highway No.8A Moraiya, Ahmedabad 382213, India ECR/147/Inst/GJ/2013/RR-19	Dr Taufik Momin
Phase II			
1	Osmania Medical College, Hyderabad–500095, Telangana	Osmania Medical College, Hyderabad–500095, Telangana ECR/300/Inst/AP/2013/RR-19	Dr R L Lakshman Rao
2	GCS Medical College, Hospital & Research Centre, Opp. DRM office, Near Chamunda bridge, Naroda road, Ahmedabad-380025	GCS Medical College, Hospital & Research Centre, Opp. DRM office, Near Chamunda bridge, Naroda road, Ahmedabad-380025. ECR/339/Inst/GJ/2013/RR-19	Dr Vipul Prajapati
3	Vidharbha Institute of Medical Sciences, Mohan Nagar, LIC Square, Kamptee Road, Nagpur – 440001, Maharashtra, India	Vidharbha Institute of Medical Sciences, Mohan Nagar, LIC Square, Kamptee Road, Nagpur-440001, Maharashtra, India ECR/1125/Inst/MH/2018	Dr Harishankar Gupta
4	Maharaja Agrasen Hospital, Vidhyadhar Nagar Marg, Sector 7, Central Spine, Vidyadhar Nagar, Jaipur, 302023	Maharaja Agrasen Hospital, Vidhyadhar Nagar Marg, Sector 7, Central Spine, Vidyadhar Nagar, Jaipur, 302023 ECR/1222/Inst/RJ/2019	Dr Manish Jain

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

I. The protocol title shall be "A prospective, randomized, adaptive, Phase I/II clinical trial to evaluate the safety and immunogenicity of Novel Corona Virus 2019-nCoV Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects".

II. The study subjects as well as the study sites for phase I & II trial shall be separate. Safety data/results after 1st dose of Phase I clinical trial shall be reviewed by DSMB, as per the protocol, and submitted to CDSCO before initiation of Phase II trial. Thereafter, safety data shall be reviewed fortnightly by DSMB.

III. Firm is required to submit revised protocol along with following information/documents & initiate the trial on satisfactory results:
   1. Copy of contract entered by sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator.
   2. Copy of valid Insurance policy for the proposed clinical trial.
   3. Revised IMP (Drug product) label including directions for ID dose (0.1 ml).
   4. RCGM recommendations as per procedure.
   5. The batches for use in the clinical trial shall be tested parallely at CDL, Kasauli in light of the COVID-19 pandemic situation.

IV. The feasibility of animal challenge studies in Non Human Primates (NHP), etc. shall also be explored & submitted to this office as and when undertaken.

V. For rapid response & fast track evaluation in light of COVID-19 pandemic, firm is required to submit the product & trial related data, as & when required by Central Licencing Authority.

Place: New Delhi
Date: 02.07.2020

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