File No: BIO/CT/20/000194

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 Ltd., Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, Opp. Ramdev Masala, Sarkhej- Bavla, N.H. No. 8A, Village - Changodar,Taluka - Sanand, Dist. Ahmedabad - 382 213, Telephone No.: null FAX: null E-Mail : sanjaymaheshwari@zyduscadila.comto conduct clinical trial of the new drug or investigational new drug as per **Protocol no. NCOV.20.002, version 01 dated 21.12.2020** in the below mentioned clinical trial sites.

CT No.: CT- 27/2020

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.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.01.04 20:03:42 +05'30'

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

Date : 04-JAN-2021
Place: New Delhi

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 by Intradermal (ID) route for 0.1ml (2mg strength by Phramajet applicator)	
Composition:	Each dose of 0.5 mL Contain	
	Name of Active ingredient	**Quantity**
	DNA plasmid construct with spike protein gene region from SARS-CoV-2 virus (Produced in *E. coli*)	5 mg
	Phosphate Buffered Saline	q.s.
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
1	Zydus Hospitals and Healthcare Research Pvt. Ltd., Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad, Gujarat- 380 054	Zydus Hospital Ethics Committee, Zydus Hospitals and Healthcare Research Pvt. Ltd., Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad, Gujarat – 380 054 ECR/ 855/Inst/GJ/20l6/RR-l9	Dr. Kalpesh Talati
2	Sumandeep Vidyapeeth an Institution Deemed to be University & Dhiraj Hospital, At & Po Piparia, Ta. Waghodia Vadodara – 391 760	Sumandeep Vidyapeeth Institutional Ethics Committee Research Cell, 2nd Floor Department of Pharmacy Sumandeep Vidyapeeth an Institution Deemed to be University, At & Po Piparia, Ta. Waghodia, Vadodara – 391 760 ECR/ l52/Inst/GJ/20l3/RR-l9	Dr. Arti Shah
3	Rhythm Heart Institute, Near Siddharth Bunglows, Sama Savli Road, Vadodara – 390 022	Rhythm Heart Institute Ethics Committee, Rhythm Heart Institute, Near Siddharth Bunglows, SamaSavli Road Vadodara – 390 022 ECR/224/Inst/GJ/2013/RR-19	Dr. Nirav Bhalani
4	GMERS Medical College and Civil Hospital, Sola, Nr Gujarat High Court, S G Highway, Sola, Ahmedabad, Gujarat – 380 060	Institutional Ethics Committee, GMERS Medical College and Civil Hospital, Sola, Department of Pharmacology, 4th Floor College Building, Nr Gujarat High Court, S G Highway, Sola, Ahmedabad, Gujarat – 380 060 ECR/404/Inst/GJ/2013/RR-20	Dr. Parul Bhatt

5	Tapan Research Centre, Tapan Multispeciality hospital and Trauma Centre, Near Platinum hall, Anandnagar Cross road, Satellite, Ahmedabad – 380 015	Vrajesh Hospital Institutional Review Board, Opp Rajpath Club, cargo Motors Lane, S.G. Road, 117 Boadakdev, Ahmedabad – 380015 ECR/1251/Inst/GJ/2019	Dr. Manish Hathila
6	Nil Ratan Sircar Medical College and Hospital, 138, Acharya Jagadish Chandra Bosce Rd, Sealdah, Kolkatta – 700 014, West Bengal	Ethics committee, NRS Medical College, 138, Acharya Jagadish Chandra Bosce Rd, Sealdah, Kolkatta – 700 014, West Bengal ECR/609/Inst/WB/2014/RR-20	Dr. Anjan Bera
7	College of Medicine & Sagore Dutta Hospital, 578, B.T. Road, Kamarhati, Kolkata – 700 058, West Bengal, India	Institutional Ethics Committee, College of Medicine & Sagore, Dutta Hospital, 578, B.T. Road, Kamarhati, Kolkata – 700 058, West Bengal, India ECR/1210/Inst/WB/2019	Dr. Sisir Chakraborty
8	Marwari Hospitals, S.J Road, Athgaon, Guwahati, Assam -781008	Marwari Hospitals, Sati Joymati Road Athgaon, Guwahati Kamrup, Metropolitan, Assam – 781 008 ECR/487/Inst/AS/2014/RR-20	Dr. Dinesh Agrawal
9	Downtown Hospital,Dispur,G S Road, Guwahati-781 006	Ethics Committee Downtown Hospital, Dispur,GS Road, Guwahati – 781 006 ECR/549/Inst/AS/2014/RR-20	Dr. Swapnav Borthakur
10	Netaji Subhash Chandra Bose Cancer Hospital. Department of Clinical Research, 3081, Nayabad, New Garia, Kolkata-700094, West Bengal, India	Ethics Committee, N.S.C.B.C. Research Institute, 3081, Nayabad, New Garia, Kolkata-700094 ERC/286/Inst/WB/2013/RR-19	Dr. Tanmoy Mandal

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

I. The Phase III clinical trial should be conducted as per protocol no. NCOV.20.002 subject to the conditions mentioned under this permission.

II. Firm should submit revise Phase III clinical trial protocol incorporating the following changes:
   a. The primary objective in the protocol should be revised to omit “irrespective to severity” and "seronegative subjects”.
   b. DSMB should be constituted to evaluate the safety data.
   c. Specify the % of adolescents between 12-18 and adults > 60 yrs of age who will be enrolled in the study.
   d. In the immunogenicity study, separate cohorts for 12-18 yrs and > 60 years should be provided.
   e. Specify the proposed action if the 2nd or the 3rd dose delayed by more than 7 days.
   f. The primary objective should be revised to first occurrence of RT-PCR positive cases 28 days of 3rd dose and accordingly, the vaccine efficacy should be assessed on data generated after Day 84 from the 1st dose.
   g. Specify the time of two interim analysis carried out.

III. Firm should continue to submit results from ongoing Phase I/II CT as per approved clinical trial protocol.

IV. Firm should submit ongoing stability (real time & accelerated) data of drug substance & drug product.
V. Firm should submit complete process validation report of Novel Corona virus-2019 nCoV vaccine.
VI. Firm should submit Insurance certificate before initiation of Phase III clinical trial.
VII. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedure.
VIII. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d033345df62d489632379a1471bfd aa6f0b2bea56c830fbba2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.01.04 20:04:06 +05'30'

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

Date: 04-DEC-2021
Place: New Delhi