

File No: BIO/CT/21/000009
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.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: Project No. 21-01, Version No. 01, Date:17-02-2021** in the below mentioned clinical trial sites.

CT No.: CT- 06/2021

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 : 15-MAR-2021
Place: New Delhi

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(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:	Novel Corona virus-2019-nCoV Vaccine		
Therapeutic class:	Vaccine		
Dosage form:	Liquid for Injection for Intradermal (ID) route of administration (using Pharmajet Tropis device). [3mg (0.3 ml) Novel Corona Virus-2019-nCov vaccine given as 3 shots of 0.1ml each via intradermal route using Pharmajet Tropis device at three different sites on the upper arm (2 shots on one arm (recommended distance between two shots is at least 5 cms) and 1 shot on other arm) at the interval of 28 days].		
Composition:	Each 0.5 mL Contains:		
	DNA plasmid construct with spike protein gene region from SARS-CoV-2 virus (Produced in <i>E. coli</i>)	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	Aartham Multi Super Speciality Hospital, Opp. Polytechnic, Nr. Panjarapole cross road, Ambawadi, Ahmedabad. 380006	Sangini Hospital Ethics Committee First Floor, Santorini Square, BH Abhishree Complex, Satellite, Ahmedabad, Gujarat. 380015 ECR/147/Inst/GJ/2013/RR-19	Dr. Jinen Mukeshbhai Shah
2	National Institute of Medical Sciences and Research (NIMS), Shobha Nagar, Jaipur-Delhi Highway, NH-11C Jaipur - 303121, Rajasthan	Institutional Ethics Committee, National Institute of Medical Sciences and Research, NIMS University, Hotam Administrative Block, Delhi-Jaipur Highway, Jaipur-303121, Rajasthan	Dr. Nalin Joshi
3	Axon Multispeciality Hospital Rukhmini Complex, Hingna Rd, near Mascott Honda, Bansi Nagar, Nagpur, Maharashtra 440016, Maharashtra	Institutional Ethics Committee of Vidharbha Institute of Medical Sciences, Mohan Nagar, LIC Square, Kamptee Road, Nagpur - 440001, Maharashtra, India	Dr. Abhishek Pande

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

- I. The Phase I/II clinical trial should be conducted as per title "A prospective, randomized, phase I/II clinical study to evaluate the safety and immunogenicity of 3mg dose of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects " protocol no.: project no. 21-01 version No. 01 dated 17-02-2021.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. The firm is required to submit Insurance certificate before initiation of clinical trial.

- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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