

File No: BIO/CT/21/000134
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. 21-10, Version No. 01, Date:17-09-2021** in the below mentioned clinical trial sites.

CT No.: CT- 34/2021

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.
4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

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Date: 30-SEP-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:	Novel Corona virus-2019-nCoV Vaccine (recombinant)		
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	Jawahar Lal Nehru Medical College & Hospital, Kala Bagh, Ajmer – 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College & Hospital, Kala Bagh, Ajmer – 305001, Rajasthan ECR/1156/Inst/RJ/2018	Dr. Veer Bahadur Singh
2	Peerless Hospitex Hospital And Research Center Limited, 360, Panchasayar, Kolkata- 700094, WB	Clinical Research Ethics Committee, Peerless Hospitex Hospital And Research Center Limited, 360, Panchasayar, Kolkata- 700094, WB ECR/232/Inst/Inst/WB/2013/RR-19	Dr Subhrojyoti Bhowmick
3	Maharaja Agrasen Hospital Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur - 302039, Rajasthan	Institutional Ethics Committee, Maharaja Agrasen Hospital Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur - 302039, Rajasthan ECR/1222/Inst/RJ/2019	Dr. Manish Kumar Jain
4	Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi (Belgaum) – 590002, Karnataka	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi – 590002, Karnataka. ECR/1242/Inst/KA/2019	Dr. Suresh G. Bhate
5	Zydus Hospitals & Healthcare Research Pvt.Ltd., Zydus Hospital Road, S.G.Highway, Thaltej, Ahmedabad- 380054, Gujarat, India	Zydus Hospital Ethics Committee, Zydus Hospitals & Healthcare Research Pvt. Ltd. Zydus Hospital Road, S. G. Highway, Thaltej, Ahmedabad- 380054, Gujarat, India	Dr. Talati Kalpesh Chimanlal

6	Pulse Multispeciality Hospital, S/N.51/7 /B/1, First Floor,Vishwa Arcade, Opp. Deccan Pavilion Hotel, Mumbai-Bangalore Highway, Narhe, Ambegaon, Pune	Institutional Ethics Committee, Survey No. 51/7/B/1 Vishwa Arcade, Bombay Bangalore Highway, At Post Narhe, Pune, Maharashtra- 411041 India	Dr. Yogesh P. Rasal
7	Sparsh Hospitals and Critical Care (P) Ltd, A/407, Sahid Nagar, Bhubaneswar-751007, Odisha	Institutional Ethics Committee, Sparsh Hospitals and Critical Care (P) Ltd., Plot No. A/407, Sahid Nager, Bhubaneswar-751007, Odisha ECR/68/Inst/OR/2013/RR-19	Dr. Bharat Das
8	Aartham Multi Super Speciality Hospital, Opp. Polytechnic, NR. Panjarapole cross road, Ambawadi, Ahmedabad. 380015	Aartham Ethics Committee Aartham Hospitals LLP Opp. Polytechnic, Near Panjarapole Cross Road, Ambawadi, Ahmedabad. 380015, Gujarat, India.	Dr. Shreyans Kirtikumar Shah
9	Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002	Institutional Ethics Committee, Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002. ECR/1017/Inst/UP/2017/RR-21	Dr. Jitendra Singh Kushwaha
10	Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, Bopal-Ghuma Road, Bopal, Ahmedabad - 380058, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, Bopal-Ghuma Road, Bopal, Ahmedabad - 380058, Gujarat ECR/1565/Inst/GJ/2021	Dr. Chintan Patel

In addition to point 4, the permission is subject to following condition(s):

- I. The Phase III clinical trial should be conducted as per title "A prospective, open-label, single arm, multicenter, phase III clinical study to evaluate the immunogenicity and safety of 3mg (2 dose) regimen of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects Project No.:21-103.Amendment No.:01 dated 17.09.2021.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. The firm is required to submit:
 - i. Insurance certificate before initiation of clinical trial.
 - ii. Publications made by firm on clinical development of IMP.
 - iii. Updated Investigator's Brochure
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)

Drugs Controller General (India)
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Date: 30-SEP-2021
Place: New Delhi