

File No: BIO/CT/22/000056
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 Zydus Lifesciences Ltd. (Formerly Cadila Healthcare Limited), Zydus Corporate Park, Scheme No. 63, Survey No. 536, Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat (India) - 382481, 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. 22-04 , version 01 dated 30.05.2022** in the below mentioned clinical trial sites.

CT No.: CT- 14/2022

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.

**VENUGOPA
L G SOMANI**

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Date: 2022.06.03 21:54:33 +05'30'

Date: 03-JUN-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).		
Composition:	Each 0.1 mL Contains:		
	DNA plasmid construct with spike protein gene region from SARS-CoV-2 virus (Produced in <i>E. coli</i>)		1 mg
	Phosphate Buffered Saline		q.s.
Indications:	For active immunization of individuals 12 years old and above for the prevention of Corona Virus Disease 2019.		

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	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
2	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
3	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
4	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 Sunil Madhab Panda
5	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. ECR/1520/Inst/ GJ/2021	Dr. Kuntal Shah

6	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
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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, randomized, open label, active controlled, multicenter, phase III clinical study to evaluate the immunogenicity and safety of single booster dose of ZyCoV-D of M/s Zydus Lifesciences Limited in adult subjects already vaccinated with 2 doses of Covaxin or Covishield" vide Protocol No. Project No.: 22-04, Version 01 dated 30.05.2022. As per protocol and commitment submitted, the interim data along with Day 84 safety will be submitted by the Firm.
- II. The Clinical trial sites shall be geographically distributed across the country.
- III. The firm is required to constitute a DSMB to review the safety data.
- IV. The firm is required to submit:
 - i. Insurance certificate before initiation of clinical trial.
 - ii. Copy of 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.
- V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures and shall have ongoing stability program.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Date: 03-JUN-2022
Place: New Delhi

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