

File No: BIO/CT/21/000142
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 Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:varma.bhupathiraju@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per protocol no. **BECT/COVID-19-PHASE-III/070** in the below mentioned clinical trial sites.

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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.

Date: 28.12.2021
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	SARS-CoV-2 (Covid-19) Vaccine (RBD antigen of SARS CoV-2 (Covid-19))	
Therapeutic class:	Vaccine	
Dosage form:	Solution for Injection by Intramuscular route	
Composition:	Each dose of 0.5 mL Contain	
	Name of Active ingredient	Quantity
	RBD antigen of SARS CoV-2 (Covid-19) ¹	25 µg
	Name of Inactive ingredients	
	Aluminium Hydroxide gel as Al++	750 µg
	CpG 1018	750 µg
	Buffer (Tris and NaCl in WFI)*	q.s to 0.5 mL
	¹ Produced in <i>Pichia pastoris</i> (Yeast). *Prepared using Sodium Chloride (B.P) - 0.9 % v/v, Tris (hydroxymethyl) aminomethane (IH) -25 mM in WFI.	
Indications:	For active immunization against COVID-19 disease 18 years and above.	

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	ESIC Medical College & Hospital Room No. 440, 4 th Floor, NH-3 behind BK Hospital New Industrial Town Faridabad -121001, Haryana, India	Institutional Ethics Committee for ESIC ESIC Medical College and Hospital, NH-3 behind BK Hospital New Industrial Town Faridabad -121001, Haryana, India ECR/1539/Inst/HR/2021	Dr. Anil Kumar Pandey
2.	Grant Medical College & Sir J.J Hospital, J J Marg, Nagpada, Mumbai Central Mumbai -400008, Maharashtra, India	Institutional Ethics Committee, Grant Govt Medical College JJ Road, JJ Hospital compound Mumbai ECR/382/1nst/MH/2013/RR-19	Dr. Khobragade Akash Ashok Kumar
3.	Apollo Hospital, Jubilee Hills, Hyderabad -500096 Telangana, India	Institutional Ethics Committee-Clinical Studies, Apollo Hospitals Enterprise Limited, Hyderabad ECR/38/Inst/AP/2013/RR-19	Dr. Suneetha Narreddy
4.	Apollo Speciality Hospital Vanagaram-Ambattur Road Ayanambakkam Chennai - 600095, Tamilnadu, India	Institutional Ethics Committee, Apollo College of Nursing Vanagaram to Ambattur Main Road, Ayanambakkam Chennai Ambattur Tiruvallur Tamil Nadu ECR/1002/Inst/TN/2017/RR-20	Dr. Jayasree Krishnan
5.	Indraprastha Apollo Hospital Sarita Vihar, Mathura Road New Delhi -110076, India	Institutional Ethics Committee, Clinical Studies- Indraprastha Apollo Hospitals, New Delhi ECR/5/Inst/DL/2013/RR-19	Dr. Viny Kantroo

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

- I. The proposed Phase III clinical trial should be conducted as per clinical trial protocol titled "A Prospective double-blind randomised Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Single Booster dose of Biological E's CORBEVAX vaccine when Administered to COVID-19-Negative Adult Volunteers Previously vaccinated with 2-doses of either COVISHIELD or COVAXIN" vide protocol no. BECT/COVID-19-PHASE-III/070.
- II. The firm is required submit revised clinical trial protocol including following points as per recommendations of SEC experts in meeting dated 27.12.2021 for initiation of proposed clinical trial
 - a. Administration of booster dose after primary immunization should be studied in 2 cohorts of 6 and 9 months with age wise stratification and including 50% subjects with high risk or comorbid condition.
 - b. Safety follow up should be extended to 9 months
- III. The firm is required submit following information/documents:
 - a. Copy of the Insurance Certificate.
 - b. Details of the 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.
- IV. DSMB shall be constituted for review of safety data of the clinical trial.
- V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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