File No: BIO/CT/21/000089
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. BECT072/Covid-19-phase-II&III/CTP-01, Version no. 1.1 dated 11.08.2021 in the below mentioned clinical trial sites.

CT No.: CT- 30/2021

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.

VENUGOPAL GIRDHARILAL SOMANI

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

Date: 01.09.2021
Place: New Delhi

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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 (recombinant RBD subunit 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 Pichia pastoris (Yeast). *Prepared using Sodium Chloride (B.P) - 0.9 % v/v, Tris (hydroxymethyl) aminomethane (IH) -25 mM in WFI.	
Indications:	For active immunization against COVIS-19 disease in children and adolescents aged ≥5 to <18 years.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	Cheluvamba Hospital Mysore Medical Collegeand research institute, Irwin Rd, Mysuru 570001, Karnataka, India.	Institutional Ethics Committee, MMC and RI and Associated Hospital Irwin Road Mysuru (Mysore) Karnataka - 570001, India. ECR/134/Inst/KA/2013/RR-19	Dr. Pradeep.N
2.	Marwari Hospital, B-3, Sati Joymati Rd, Athgaon, Guwahati 781001, Assam, India.	Hospital Ethics Committee, Marwari Hospital, B-3, Sati Joymati Rd, Athgaon, Guwahati 781001, Assam, India. ECR/487/Inst/AS/2013/RR-19	Dr. Ritesh Kumar Jain
3.	GTB Hospital attached to UCMS, TahirpurRd, GTB Enclave, Dilshad Garden, Delhi 110095, India.	Institutional Ethics Committee, Guru Teg Bahadur Hospital Ethics Committee,Guru Teg Bahadur Hospital Dilshad Garden Delhi East Delhi -110095 India. ECR/510/Inst/DL/2014/RR-20	Dr. Manish Narang,
4.	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, J N Medical College,Nehru Nagar, Belagavi -590010, Karnataka, India	Institutional Ethics Committee, KLE University KLE Dr.PK Hospital and MRCNehru Nagar Belagavi (Belgaum) Karnataka -590010 India. ECR/211/Inst/KA/2013/RR-19	Dr. N S Mahantshetti
5.	Sant Dynaneshwar Medical Research Centre, 695-A Sadashiv Peth, Opposite Vijay Talkies, Laxmi Road, Pune 411030, Maharashtra, India	Sant DnyaneshwarMedical Education Research Centre,695-A, Sadashiv Peth, Laxmi Road, OPP. Vijay Talkies, Pune Maharashtra - 411030. India ECR/127/Inst/MH/2013/RR-19	Dr. Ramchandra Keshav Dhongade

6.	Govt. Medical college, medical square, Ajni road, Nagpur-440003.	Institutional Ethics Committee, Government Medical College and Hospital, Nagpur.Medical Square, Hanuman Nagar,Maharashtra -440003 India. ECR/43/Inst/MH/2013/RR-19	Dr. Uday Wasudevrao Narlawar
7.	JSS Hospital,MG Road,Mysuru-570004.	Institutional Ethics Committee JSS Medical College and HospitalSri Shivarathreeshwara Nagar,Mysore, Karnataka -570015 India. ECR/387/Inst/KA/2013/RR-19	Dr. M. D. Ravi
8.	St Theresa's Hospital, Sanath Nagar, Hyderabad 500018, Telangana, India.	Ethics Committee, ST.Theresas HospitalSanath Nagar Opp Erragadda Raitu BazarHyderabad Telangana - 500018 India. ECR/230/Inst/AP/2013/RR-19	Dr. G. Bala Kishor
9.	National Institute of Medical Sciences (NIMS), Shobha Nagar, Jaipur, Delhi Highway, NH-11C, Jaipur 303121, Rajasthan.	Institutional ethics committee,National Institute of Medical Sciencesand research,NIMSuniversityHotam administrative block,Jaipur303121, Delhi highway, Rajasthan. ECR/665/Inst/RJ/2014/RR-17	Dr. Yograj Khinchi
10.	Subham Sudbhawana Superspeciahy Hospilal, B31/80,23B-BhogabirLanka, Varanasi-221005, UP.	Shubham Sudbhawana Super. Hosp. EthicsCommittee,Shubham Sudbhawana Superspeciality Hospital, B 31/80, 23B - Bhogabeer, Lanka, Varanasi-221005,U.P. Varanasi Uttar Pradesh -221005 India. ECR/667/Inst/UP/2014/RR-20	Dr. Madhukar Pandey

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

I. The Phase II/III clinical trial should be conducted as per approved protocol titled "A Prospective, Randomised, Double-blind, Placebo controlled, Phase-II by III Study to Evaluate Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX Vaccine in Children and Adolescents" vide protocol no. BECT072/Covid-19-phase-II&III/CTP-01, Version no. 1.1 dated 11.08.2021.

II. The firm is required submit following data/documents:

   a. Constitute a DSMB to review the safety data of Phase II/III clinical trial.
   b. Copy of the Insurance Certificate.
   c. 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.

III. 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.

IV. 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: 01.09.2021
Place: New Delhi

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