

File No: BIO/CT/21/000103

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/074 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.

Date: 20-AUG-2021  
Place: New Delhi

(Dr. V. G. Somani)  
Drugs Controller General (India)  
Central Licencing Authority  
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**Annexure: Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (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 Contains	
	<b>Ingredients</b>	<b>Quantity</b>
	RBD antigen of SARS CoV-2 (Covid-19)	25 µg
	Aluminium Hydroxide gel as Al <sup>++</sup>	750 µg
	CpG 1018	750 µg
	Buffer (Tris and NaCl in WFI)	q.s to 0.5 mL
Indications:	For active immunization against SARS-CoV-2 (COVID-19) in adult aged 18 years.	

**Details of clinical trial sites-**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Institute of Medical Sciences and SUM Hospital, Siksha Anusandhan deemed to be University, K-8, Kalinga Nagar, Ghatikia, Bhubaneswar, Odisha -751003	Institutional Ethics Committee, Institute of Medical Sciences & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar 751003, Odisha, India ECR/627/Inst/OR/2014/RR-20	Dr.Jyotiranjan Sahoo
2	Prakhar Hospital Pvt Ltd, 81219, Arya Nagar Rd, Khalasi Line, Arya Nagar, Kanpur, Uttar Pradesh-208002, India	Institutional Ethics Committee, Prakhar Hospital PvtLtd Prakhar Hospital Pvt. Ltd 8/219 Arya Nagar Kanpur Kanpur Kanpur Nagar Uttar Pradesh-208002 India ECR/1017/Inst/UP/2017/RR-21	Dr.J.S Khushwaha
3	GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India	GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India ECR/1017/Inst/UP/2017/RR-21	Dr.Shiva Narang
4	Dayanand Medical College & Hospital, Department of Medicine, Civil Lines, Tagore Nagar, Ludhiana -141001, Punjab	Ethics Committee Guru Teg Bahadur Hospital Dilshad Garden, Delhi -110095 India ECR/510/Inst/DL/2014/RR-20	Dr.Dinesh Jain
5	ESIC Medical College & Hospital, NH-3, NIT, Faridabad, Haryana, India-121001	Institutional Ethics Committee for ESIC Medical College and Hospital, NH-3 NIT Behind BK Hospital Faridabad 121001, Haryana, India ECR/1539/Inst/HR/2021	Dr. Anil Kumar Pandey
6	Shubham Sudbhawana Superspecialiry Hospital. B 31/80, 238. Bhogabeer, Lanka, Varanasi-22 1005. Unar pradesh, India.	Shubham Sudbhawana Super. Hosp. Ethics Committee, B 31/80, 23B -Bhogabeer, Lanka, Varanasi, 221005, India. ECR/667/Inst/UP/2014/RR-20	Dr. Indranil Basu
7	St. Theresa's Hospital,	Ethics Committee, St. Theresa's	Dr. A.

	Sanathnagar, Hyderabad 500018 Telangana State, India.	Hospital, Sanath Nagar, Opp. Erragada Raitu Bazar, Hyderabad 500018, Telangana, India ECR/230/Inst/AP/2013/RR-19	Venkateshwara Rao
8	King George Hospital Maharanipeta Collector Office Junction Visakhapatnam, Andhra Pradesh -530002 India	Institutional Ethics Committee, King George hospital Visakhapatnam - 530002 Andhra Pradesh, India. ECR/197/Inst/KGH/2013/RR-20	Dr. R Vasudev
9	KLE University KLE Dr.PK Hospital and MRCNehru Nagar Belagavi (Belgaum) Karnataka - 590010 India,	Institutional Ethics Committee, KLE University KLE University KLE Dr. PK Hospital and MRC Nehru Nagar Belagavi 590010 Karnataka, India ECR/211/Inst/KA/2013/RR-19	Dr. Madhav Prabhu,
10	Asian Institute of Gastroenterology 6-3-661 Somajiguda Hyderabad, Telangana-500082, India.	Institutional Ethics Committee, Asian Institute of Gastroenterology, 6-3-661, Somajiguda, Hyderabad 500082, Telangana, India ECR/346/Inst/AP/2013/RR-19	Dr. P. Naveen Chander Reddy
11	Belagavi Institute of Medical Sciences, Dr B R Ambedkar Road. Belagavi-59000 IKarnataka, India	Belgavi Institute of Medical Sciences, Dr B R Ambedkar Rd, Sadashiv Nagar, Belagavi - 590019, Karnataka, India	Dr. Rachgonda G. Viveki
12	National Institute of Medical Sciences and Research (NIMS), Shobha Nagar, Jaipur-Delhi Highway NH-11C Jaipur - 303121 Rajasthan	IEC NIMS University, Hotam administrative block, Delhi-Jaipur highway, Jaipur-303121, Rajasthan, India. ECR/665/Inst/RJ/2014/RR-17	Dr. Rajendra Dhar
13	Sri Ramachandra Hospital Ramachandra Nagar, Porur, Chennai -600116	Institutional Ethics Committee SRIHER, Ramachandra Nagar, Porur Chennai 600116, Tamil Nadu, India. ECR/203/Inst/TN/2013/RR-19	Dr. R. B. Sudagar Singh
14	Govt Medical College, Hanuman Nagar, Ajani Rd, Medical Chowk, Ajni, Nagpur 440003, Maharashtra, India.	Institutional Ethics Committee, Government Medical College and Hospital, Nagpur, Government Medical College Medical Square, Hanuman Nagar Nagpur 440003, Maharashtra, India ECR/43/Inst/MH/2013/RR-19	Dr. Uday Wasudevrao Narlawar
15	Yashwantrao Chavan Memorial Hospital, Pimpri, Sant Tukaram Nagar, Near D.Y Patil Medical College, Vallabhnagar, Near Fire Brigade Station, Pimpri, Pune-411018, Maharashtra, India	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Pimpri. Sant Tukaram Nagar, Near D.Y.Patil Medical College, Vallabhnagar, Near Fire Brigade Station, Pimpri Pune 411018, Maharashtra India. ECR/1236/Inst/MH/2019	Dr. Pravin Soni
16	Grant Medical College & Sir J.J Hospital, Mumbai, Maharashtra, India.	Institutional Ethics Committee, Grant Medical College & Sir J.J Hospital, J J Marg, Nagpada, Mumbai Central, Mumbai 400008,	Dr. Khobragade Akash Ashok Kumar

		Maharashtra, India	
17	TN Medical College & BYL Nair Hospital, Dr. A. L, Dr Anandrao Nair Marg, RTO Colony, Mumbai Central, Mumbai-400008, Maharashtra, India	Institutional Ethics Committee TNMC NAIR HOSPITAL, Topiwala National Medical College Nair Hospital Dr A L Nair Road Mumbai Central Mumbai City Maharashtra - 400008 India	Dr. Renuka Munshi
18	JLN Medical College, Kala Bagh, Ajmer 305001, Rajasthan, India	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh Ajmer -305001, Rajasthan, India ECR/1156/Inst/RJ/2018	Dr. Veer Bhadur Singh
19	Christian Medical College & Hospital, Brown Rd, CMC Campus, Ludhiana - 141008, Punjab, India	Institutional Ethics Committee Christian Medical College & Hospital, Brown Rd, Ludhiana - 141008, Punjab, India ECR/120/Inst/PB/2013/RR-19	Dr. Clarence.J Samuel
20	Apex Hospital, SP 4 & 6 MIA Malviya Nagar near apex circle, Jaipur -302017, Rajasthan, India	Institutional Ethics Committee, Apex Hospitals Private Limited, SP 4 and 6 Industrial Area, Malviya Nagar Jaipur -302017, Rajasthan, India ECR/380/Inst/RJ/2013/RR-19	Dr. Vipul Khandelwal
21	Medanta Institute of Education and Research, Sector 38, CH Baktawar Singh Rd, Medicity, Islampur Colony, Sector 38, Gurgaon -122018, Haryana	Medanta Institutional Ethics Committee Medanta-The Medicity, Medanta-The Medicity Sector 38 Gurugram 122001, Haryana ECR/282/Inst/HR/2013/RR-20	Dr. Sushila Kataria
21	Tata Memorial Centre, Parel East, Parel, Mumbai 400012, Maharashtra, India	Institutional Ethics Committee III, TMC ACTREC Tata Memorial Centre, ACTREC Sector 22, Near Owe camp Kharghar, Navi Mumbai 410210, Maharashtra, India ECR/149/Inst/MH/2013/RR-19	Dr. Gauravi Mishra
23	BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg, Adajanchar rasta. Adajan. Surat-395 009, Gujarat, India	BAPS Hospital Institutional Ethics Committee, BAPS Pramukh Swami Hospital, Adajan Cross Road, Surat 395009, Gujarat India. ECR/639/Inst/GJ/2014/RR-20	Dr. Parshottam Koradia
24	Christian Medical College Vellore Association, IDA Scudder Rd, Vellore 632004, Tamil Nadu, India	RB Christian Medical college, Office of research, 1st floor, carman block, bagayam, Vellore 632002, Tamilnadu, India. ECR/RENEW/INST/2019/3526	Dr. Winsley Rose
25	JSS Hospital, Mahatma Gandhi Road, Fort Mohalla, Mysuru-570004, Karnataka, India	Institutional Ethics Committee JSS Medical College, JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar, Mysuru (Mysore) -570015, Karnataka, India ECR/387/Inst/KA/2013/RR-19	Dr Shilpa Avarebeel

26	Mahatma Gandhi Institute of Medical Sciences (MGIMS), Sewagram, Wardha 442102, Maharashtra, India	IEC, Mahatma Gandhi institute of medical sciences, Sewagram, Wardha, Maharashtra-442102, India ECR/47/Inst/MH/2013/RR-19	Dr. Bishan Swarup Garg
27	Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), Dhanvantari Nagar, Puducherry-605006, India	IEC Intervention Studies JIPMER, JIPMER Dhanvantari Nagar Pondicherry Puducherry -605006 India, ECR/342/Inst/PY/2013/RR-19	Dr. Venkateshwaran.R
28	All India Institute of Medical Sciences (AIIMS), Department of Community & Family Medicine, Aurangabad Road Phulwari Sharif, Patna 801507, Bihar, India	IEC-AIIMS-PATNA All India Institute of Medical Sciences, Patna 801507, Bihar India ECR/1387/Inst/BR/2020	Dr.Chandramani Singh
29	Samvedna Hospital, B-27/88-G, New Colony, Varanasi-221005, Uttar Pradesh, India	Samvedna Hospital Ethics Committee, SamvedanaHospital, B2788G, Ravidra puri, Varanasi 221005, Uttar pradesh, India ECR/45/Inst/UP/2013/RR-20	Dr. Monica Gupta
30	B J Govt Medical College and Sassoon General Hospitals College, Jai Prakash Narayan Road, Near Pune Railway Station, Pune 411001, Maharashtra, India	IEC BJ Medical College and SGH, B.J govt college and Sassoon General hospitals, Jai prakash Narayan road, Pune maharashtra-411001, India ECR/433/Inst/MH/2013/RR-19	Dr. Rohidas Borse

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

- I. The Phase III comparator clinical trial should be conducted as per protocol titled "A Prospective, Single-blind, Randomized, Active-controlled Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to RT-PCR Negative Adult Subjects." vide protocol no. BECT/COVID-19-PHASE-III/074.
- II. As per recommendations of the Subject expert committee (SEC) meeting dated 19,08,2021 firm is required to submit revised clinical trial protocol incorporating the following:
  - Immunogenicity assessment shall be carried out at day 90 also.
  - Adverse events of special interest (AESI) should be monitored.
  - The trial participants should be stratified in three age groups, 18-45, 45- 65 and >60 years and there should be adequate representation of both the sexes
- III. The firm is required to comply & submit following data/documents:
  - a. Ensure the stability of the proposed vaccine and to submit the Real time and accelerated stability data of final lot of SARS-CoV-2 (COVID-19) vaccine of single dose and multi dose presentations periodically.
  - 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.
- IV. DSMB should be constituted for review of the safety data of the clinical trial

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- 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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