File No: BIO/CT/23/000118
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 Mr. Varma B S S S Bhupathiraju of M/s Biological E Limited, Plot No 1, Biotech Park, Phase II Kolthur Village, Shameerpet, Medchal-Malkajgiri District: Telangana -500078 to conduct Phase-III clinical trial of the new drug or investigational new drug as per Protocol No: BECT083/XBB-COVID-19-PHASE-III/CTP-01, Version No. 1.1 Dated 20.12.2023in the below mentioned clinical trial sites.

CT No.: CT- 17/2023

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.

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Place: New Delhi
Date: Central Licencing Authority

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	SARS-CoV-2 (Covid-19) Vaccine (Variant XBB.1.5)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Injection (Intramuscular)	
Composition:	Each dose of 0.5 ml contains	
	Name of active ingredient	**Quantity**
	RBD antigen of SARS CoV-2 (Covid-19) (Strain RBD-XBB.1.5)*	25 µg
	Name of inactive ingredient	**Quantity**
	Aluminium Hydroxide gel as Al^{+++}	750 µg
	CpG 1018	750 µg
	Buffer (Tris and NaCl in WFI)	q.s to 0.5 ml
	*Produced in *Pichia pastoris* (Yeast)	
Indication(s):	Active Immunization against infections caused by XBB.1.5 variant of SARS-CoV-2 (Covid-19).	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	BAPS Pramukh Swami Hospital, Adajan Cross Road, Adajan Surat, Gujarat - 395009 India.	BAPS Hospital Institutional Ethics Committee, BAPS Pramukh Swami Hospital, Adajan Surat Gujarat - 395009 India. [ECR/639/Inst/GJ/2014/RR-20]	Dr.Parshottam Govindbhai Koradia
2	Cheluvamba Hospital, Irwin Rd, Devraj Mohalla, Mysuru 570001, Karnataka, India.	IEC-MMC & RI,Mysore Medical College and Research Institute, Irwin Road, Mysore,Karnataka – 570001. [ECR/134/Inst/KA/2013/RR-19]	Dr. Pradeep Nanjappa
3.	ESIC Medical College and HospitalNH-3 NIT Behind BK Hospital Faridabad 121001, Haryana, India.	Institutional Ethics Committee,ESIC Medical College and Hospital, 4th Floor, NH-3, NIT, Behind BK Hospital,Faridabad, Haryana – 121001 [ECR/1539/Inst/HR/2021]	Dr. Anil Kumar Pandey
4.	Gillurkar Multispeciality Hospital, Plot no. 20, Reshimbag, Umred Road, Nagpur, Maharashtra 440009, India.	Ethics Committee, Gillurkar Multispeciality Hospital, Plot No. 20, Reshimbag Umred Road,Nagpur, Maharashtra – 440009 [ECR/1374/Inst/MH/2020]	Dr. Chandrashekhar S. Gillurkar

5.	Guru Teg Bahadur Hospital, Dilshad Garden, Delhi East - 110095 India.	Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, Delhi East, Delhi – 110095 [ECR/510/Inst/DL/2014/RR-20]	Dr. Manish Narang
6.	LifePoint Multi-Specialty Hospital Pvt. Ltd. 145/1, Mumbai-Bangalore highway , Near Hotel SayajiWakad Pune; Maharashtra - 411057 India.	Ethics Committee, LifePoint Multispecialty Hospital Pvt. Ltd., 145/1, Mumbai BangaloreHighway, Near Hotel Sayaji, Wakad, Pune, Maharashtra – 411057. [ECR/751/Inst/MH/2015/RR-21]	Dr.Sachin Kisan Shivnitwar.
7.	St. Theresa's Hospital, Sanath Nagar, Opp. Erragada Raitu Bazar, Hyderabad 500018, Telangana, India.	Ethics Committee, St. Theresa's Hospital, Sanathnagar, Opp. Erragadda Raitu Bazar, Hyderabad, Telangana– 500018 [ECR/230/Inst/AP/2013/RR-22]	Dr. A. Venkateshwara Rao

In addition to point 3, the permission is subject to following conditions:

I. The clinical trial should be conducted as per approved protocol titled "A Prospective, single-blind randomized phase - III comparative study to evaluate immunogenicity and safety of Biological E's XBB.1.5 - RBD subunit COVID-19 vaccine in 5-80 years old individuals (Protocol No. BECT083/XBB-COVID-19-PHASE-III/CTP-01, Ver. 1.1, Dated 20.12.2023).
II. The firm is required to constitute a DSMB to review the safety data.
III. 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.
IV. Firm shall submit copy of Insurance Certificate.
V. CDL report of the batches shall be submitted.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.
VII. Firm is required to submit Ethics Committee approval for clinical trial.

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: