

File No: BIO/CT/25/000083
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002

To,

M/s. Biological E. Limited,
Sy. No. 549, 550, 552 to 556,
Kolthur Village, Shameerpet,
Medchal-Malkajgiri (District), Telangana-500078

Subject: Permission for conducting a phase III clinical trial titled "A prospective single-blind randomized Phase-III comparative study to evaluate immunogenicity and safety of Biological E's JN.1-RBD subunit Covid-19 vaccine in 18-80 years old individuals". (Protocol no. BECT092/JN.1-Covid-19-Phase-III/CTP-02, Version no.2.0 dated 11.06.25) -regarding.

Reference: Your application No. BIO/CT04/FF/2025/49495 dated 13-May-2025 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2025/49495 dated 13.05.2025. In this regard, please find enclosed herewith permission to conduct a Phase III clinical trial of SARS-CoV-2 (Covid-19) Vaccine (Variant JN.1) in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs and Cosmetics Rules, 1945 and communication of Central Licencing Authority.

Please acknowledge receipt of the same.

Yours faithfully,

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

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 grant permission to M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India –500078; Telephone No.: 91-40-67388000, FAX: 91-40-30128159, E-mail: info@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per Protocol no. BECT092/JN.1-Covid-19-Phase-III/CTP-02, Version no. 2.0 dated 11.06.25 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT-16/2025

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 trials 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 with automatically be granted to you.

Date:
Place: New Delhi

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing 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 JN.1)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular injection	
Composition:	Each dose of 0.5 mL Vaccine contains:	
	Ingredients	Quantity
	RBD antigen of SARS-CoV-2 (Covid-19) (Strain RBD-JN.1) ¹	25 µg
	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	
Indication:	Active immunization against infections caused by JN.1 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	JLN Medical College, Kala Bagh-305001, Ajmer, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan - 305001, India. [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Anil Samaria MBBS, MD (General Medicine)
2	King George Hospital Collectorate Junction, Maharanipecta, Visakhapatnam - 530002, Andhra Pradesh.	Institutional Ethics Committee King George Hospital Visakhapatnam, Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. P. Jagath Srinivas M.B.B.S, MD (Community Medicine)
3	SSG General Hospital, Anandpura, Vadodara 390001, Gujarat, India.	Institutional Ethics Committee for Human Research, Department of Pediatrics, Ward 17, First Floor, Medical College & SSG Hospital, Vadodara 390001, Gujarat, India. [ECR/85/Inst/GJ/2013/RR-24]	Dr. Keyur Brahme MBBS, MD (General Medicine)
4	St. Theresa's Hospital (STH), 1st Floor, Room No. 05, Erragadda Main Road, Sanath Nagar, Hyderabad 500018, Telangana, India.	Ethics committee, St Theresa's Hospital, Sanathnagar, Opp. Erragadda Raitu Bazar, Hyderabad, Telangana -500018, India. [ECR/230/Inst/AP/2013/RR-22]	Dr. A. Venkateshwar Rao MBBS, DNB (Internal Medicine)

5	BGS Global Institute of Medical Sciences, Dept of Paediatrics, No. 67, BGS Health and Education city Uttarahalli Road Kengeri Bangalore- 560060 India	Institutional Ethics Committee BGS Global Institute of Medical Sciences ,67 BGS Health and Education City Uttarahalli Road Kengeri Bangalore South Karnataka Bengaluru (Bangalore) Urban Karnataka - 560060 India [ECR/1307/Inst/KA/2019/RR-24]	Dr. Harshith C.S MBBS, MD (General Medicine)
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In addition to point 4, the permission is subject to following condition(s):

- 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 JN.1-RBD subunit Covid-19 vaccine in 18-80 years old individuals. (Protocol no. BECT092/JN.1-Covid-19-Phase-III/CTP-02, Version no. 2.0 dated 11.06.25).
- II. Only CDL, Kasauli tested consistency batches shall be used in Phase-III clinical trial.
- III. To submit Ethics Committee approval for proposed Phase-III Clinical trial.
- IV. DSMB shall be constituted for review of Phase III safety data.
- V. To submit complete certificate of analysis of In-house reference standard (IRHS).
- VI. To submit characterization data of research cell bank along with COA of RCB, MCB & WCB.
- VII. Process Validation Report of commercial scale batches shall be submitted.
- VIII. To submit the ongoing real time/accelerated stability data and stability failures, if any, shall be informed to this office forthwith along with root cause analysis.
- IX. The available long term stability data should cover the duration of study.
- X. To submit bioanalytical method validation report for ELISA & PSVNT₅₀.
- XI. To submit re-registration certificate of IEC King George Hospital, Collectorate Junction, Maharanipecta, Visakhapatnam-530002, Andhra Pradesh, India before initiation of study.

Date:
Place: New Delhi

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