File No: BIO/CT/25/000012
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
Dated:

To

M/s Biological E. Limited, Plot no.1,
Biotech Park, Phase II, Kolthur Village,
Shameerpet, Medchal-Malkajgiri District,
Telangana, India – 500078.

Subject: Permission for conducting a clinical trial titled "A prospective open-label, randomized, controlled Phase-I clinical study to evaluate the safety, tolerability and reactogenicity of single dose of Biological E's Yellow Fever Vaccine administered to 18-45 years-old healthy adults.". [Protocol No. BECT093/YFV-Phase-I/CTP-02, Version: v2.0 dated 07.05.2025]"- regarding.

Reference: Your Application No. BIO/CT04/FF/2025/47422 dated 28-JAN-2025 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2025/47422 dated 28-JAN-2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Yellow Fever Vaccine, Live, Attenuated (Freeze-dried)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.09.08 10:22:25 +05'30'

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

File No: BIO/CT/25/000012
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, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India -500 078 India Tel: 91-40-67388000 Fax: 91-40-30128159 to conduct clinical trial of the new drug or investigational new drug as per protocol number: BECT093/YFV-Phase-I/CTP-02, Version: v2.0 dated 07.05.2025 in the below mentioned clinical trial sites.

CT No.: CT-15/2025

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.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Yellow Fever Vaccine, Live, Attenuated (Freeze-dried)
Therapeutic class:	Vaccines (Viral Vaccines)
Dosage form:	Vial
Composition:	Each reconstitution dose of 0.5 ml vaccine contains:

Ingredients	Quantity
Yellow Fever 17-D strain bulk antigen (Live, Attenuated)	NLT 1000 IU
Sodium Bicarbonate	0.17 mg
Citric acid	0.085 mg
Disodium hydrogen orthophosphate anhydrous	0.45 mg
Hydrolyzed Gelatin	20.0 mg
D-sorbitol	12.5 mg
Sucrose	5.0 mg
Dextrose anhydrous	0.33 mg
Human albumin solution	0.31 mg
Reconstitute the Vaccine Vial with the diluent (0.9% W/V Sodium Chloride Injection)	

Presentation:	Single Dose - 0.5 mL(Lyophilized)
Indication(s):	Vaccine intended for active immunization against Yellow Fever disease.

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	UCMS & GTB Hospital, Dilshad Garden, Delhi - 110095, India.	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital Dilshad Garden Delhi East Delhi Delhi – 110095 India ECR/510/Inst/DL/2014/RR-20	Dr. Shiva Narang M.B.B.S & MD (General Medicine)
2	King George Hospital Collectorate Junction, Maharanipeta, Visakhapatnam – 530002 Andhra Pradesh, India	IEC King George hospital King George Hospital Maharanipeta Collector Office Junction Visakhapatnam Andhra Pradesh - 530002 India ECR/197/Inst/KGH/2013/RR- 20	Dr. Pentakota Jagath Srinivas M.B.B.S & M.D (Community Medicine)
3	St.Theresas Hospital (STH), 1st Floor, Room No. 05, Erragadda Main Road, Czech Colony	Ethics committee St Theresas Hospital Sanathnagar, Opp. Erragadda Raitu Bazar	Dr. A. Venkateshwar Rao M.B.B.S &

	Sanath Nagar, Hyderabad 500038, Telangana, India	Hyderabad, Telangana - 500018 India ECR/230/INST/AP/2013/RR-22	DNB (Internal Medicine)

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

1. The Phase-I clinical trial should be conducted as per approved protocol titled “A prospective open-label, randomized, controlled Phase-I clinical study to evaluate the safety, tolerability and reactogenicity of single dose of Biological E’s Yellow Fever Vaccine administered to 18-45 years-old healthy adults”(Protocol No: BECT093/YFV-Phase-I/CTP-02, Version: v2.0 dated 07.05.2025).
2. A data safety monitoring board (DSMB) will be constituted to review the safety data for all the enrolled subjects in the study.
3. Firm shall submit Ethics Committee approval for proposed Phase-I clinical trial.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have on-going stability programme to ascertain that the available long term stability data cover the entire duration of clinical trial.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date: