File No: BIO/CT/24/000036
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

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

To,

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

Subject: Permission for conducting a phase I clinical trial titled "A prospective multicentre, open label, Phase-I study to evaluate the safety and immunogenicity of Biological E's Bivalent Typhoid and Paratyphoid A conjugate vaccine administered to 18-55 years-old healthy adults in India" [Protocol no. BECT086/Bi-TCV-Phase-I/CTP-01, Version No. 1.0 Final dated 09.12.24]- regarding.

Reference: Your Application No. BIO/CT04/FF/2024/42545 dated 25-03-2024 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2024/42545 dated 25-03-2024 received by this office on the above subject. Please find enclosed herewith permission to conduct phase I clinical trial of "Typhoid and Paratyphoid A Conjugate Vaccine (Bivalent)" 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
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.05.15 17:36:03 +05'30'

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

File No: BIO/CT/24/000036
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 -500078, India; 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: BECT086/Bi-TCV-Phase-I/CTP-01, Version No.: 1.0 Final dated 09.12.24 in the below mentioned clinical trial sites.

CT No.: CT- 07/2025

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.

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

Place: New Delhi
Date

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Typhoid and Paratyphoid A Conjugate Vaccine (Bivalent)	
Therapeutic class:	Vaccine	
Dosage form:	Solution for Intramuscular injection	
Composition:	**Each dose of 0.5 mL Vaccine contains:**	
	Composition	**Quantity**
	Ingredients	
	Typhoid Vi Polysaccharide[1] Conjugated to CRM_{197}	25 µg
	O:2 Polysaccharide[2] Conjugated to CRM_{197}	25 µg
	2-Phenoxyethanol (As Preservative)	4 mg
	154 mM Sodium chloride	4.5 mg
	[1]Produced from *C. freundii sesnu lato* 3056 [2]Produced from *S. Paratyphi A*	
Presentation	0.5 mL Single dose vial presentation.	
Indication	Typhoid and Paratyphoid A Conjugate Vaccine (Bivalent) is indicated for active immunization against enteric fever.	

Details of clinical trial sites-

S. No.	Names and address of clinical trial sites	Ethics committee details	Name of Principal Investigator(s)
1.	GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India.	Institutional Ethics Committee, GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India [ECR/510/Inst/DL/2014/RR-20]	Dr. Shiva Narang M.B.B.S, M.D (Paediatrics)
2.	King George Hospital Collectorate Junction, Maharanipeta, Visakhapatnam- 530002, Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital Collectorate Junction, Maharanipeta, Visakhapatnam - 530002, Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. P.J. Srinivas M.B.B.S & M.D (Community 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 multicentre, open label, Phase-I study to evaluate the safety and immunogenicity of Biological E’s Bivalent Typhoid and Paratyphoid A conjugate vaccine administered to 18-55 years-old healthy adults in India” [Protocol no. BECT086/Bi-TCV-Phase-I/CTP-01, Version No. 1.0 Final dated 09.12.24].
2. The firm shall constitute a DSMB to review the safety data.
3. The firm shall submit Ethics Committee approval for Phase I clinical trial.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.
6. The firm shall submit Developmental and Reproductive Toxicity (DART) study report in animal for Typhoid and Paratyphoid A Conjugate Vaccine (Bivalent).

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date