File No: BIO/CT/21/000060
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. **BECT064TCVPhase-IV version 1.1 dated 20.09.21** in the below mentioned clinical trial sites.

CT No.: CT- 40/2021

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 trial 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 will automatically be granted to you.

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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Date: 01-Dec-2021
Place: New Delhi

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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug	Typhoid Conjugate Vaccine (Monovalent) [Typhoid Vi Conjugate Vaccine]	
Therapeutic class	Vaccine	
Dosage form	Suspension for Intramuscular Injection Presentation: Single dose (0.5ml)	
Composition	Each dose of 0.5 mL contains:	
	Name of ingredient	**Quantity**
	Typhoid Vi Polysaccharide[1] conjugated to 16.7µg –100 µg of CRM_{197} [1]Produced from *C. freundii sensu lato 3056*	25 µg
	Sodium Chloride and Phosphate Buffer	q.s
	2-Phenoxyethanol	5 mg
Indications	For active immunization against infection caused by *Salmonella typhi* in infants children adolescents and adults (6 months to ≤45 years of age).	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	King George Hospital (KGH), Near Collectorate Junction, Maharanipeta, Visakhapatnam –530002, Andhra Pradesh, India.	Intuitional Ethics Committee, King George hospital, King George Hospital Maharani peta Collector Office Junction Visakhapatnam, Andhra Pradesh -530002 India	Dr Vasu Dev
2.	Institute of Medical Sciences & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar - 751003, Odisha, India	Institute of Medical Sciences & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar - 751003, Odisha, India [ECR/627/Inst/OR/2014/RR-20]	Dr. Sandeep Kumar Panigrahi
3.	Cheluvamba Hospital, Irwin Rd, Devraj MohallaMysuru - 570001, Karnataka, India	Intuitional Ethics Committee, Cheluvamba Hospital Irwin Rd, Devraj Mohalla Mysuru -570001, Karnataka, India	Dr. Pradeep. N
4.	Guru Teg Bahadur Hospital, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India	Guru Teg Bahadur Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, North East Delhi –110095, India	Dr. Manish Narang
5.	Vijay Vallabh Hospital, Tirupati Nagar Rd, beside Banjara Hotel, Phase 1, Tirupati Nagar, Virar West, Mumbai -401303, Maharashtra, India	Ethics Committee, Vijay Vallabh Hospital Tirupati Nagar Rd, beside Banjara Hotel, Phase 1, Tirupati Nagar, Virar West, Mumbai - 401303, Maharashtra, India	Dr. Gaurav Sharma
6.	Dana Shivam Heart & Super specialty Hospital, Plot No:2, Opp. Times Square, Sector 2, Vijay Bari, Vidyadhar Nagar, Jaipur -302023, Rajasthan, India	Intuitional Ethics Committee, Dana Shivam Heart & Super specialty Hospital, Plot No:2, Opp. Times Square, Sector 2, Vijay Bari, Vidyadhar Nagar, Jaipur -302023, Rajasthan, India	Dr. Chandra Prakash Suthar

7.	Elite Mission Hospital, Koorkenchery Rd, Koorkenchery, Thrissur - 680007, Kerala, India	Intuitional Ethics Committee, Elite Mission Hospital, Koorkenchery Rd, Koorkenchery, Thrissur -680007, Kerala, India	Dr. Satish Chandran
8.	Govt Medical College, Hanuman Nagar, Ajani Road Medical Chowk, Ajni, Nagpur - 440003, Maharashtra, India	Intuitional Ethics Committee, Govt Medical College, Hanuman Nagar, Ajani Road Medical Chowk, Ajni, Nagpur -440003, Maharashtra, India	Dr. Uday Wasudevrao Narlawar
9.	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, J N Medical College, Nehru Nagar, Belagavi – 590010 Karnataka, India	Intuitional Ethics Committee, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, J N Medical College, Nehru Nagar, Belagavi –590010 Karnataka, India	Dr. N. S. Mahantshetti
10.	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, – 305001 Rajasthan, India	Intuitional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, – 305001 Rajasthan, India	Dr. Veer Bahadur Singh
11.	YCM Hospital, Sant Tukaram Nagar, Pimpri Colony, Pune - 411018, Maharashtra, India	Intuitional Ethics Committee, YCM Hospital, Sant Tukaram Nagar, Pimpri Colony, Pune - 411018, Maharashtra, India	Dr. Seema Soni
12.	Chettinad Hospital and Research Institute SH 49A, Kelambakkam Chennai - 603103, Tamil Nadu, India	Intuitional Ethics Committee, Chettinad Hospital and Research Institute SH 49A, Kelambakkam Chennai - 603103, Tamil Nadu, India	Dr. M. Alexander

In addition to point 4, the permission is subject to following condition(s):

I. The Phase IV clinical trial should be conducted as per approved protocol titled " A prospective multicentre phase-IV clinical study to evaluate the safety of single intramuscular dose of Biological E's typhoid conjugate vaccine in 6 months to 45 years old participants and its impact on measles immunogenicity when co-administered with licensed Measles-Rubella (MR)vaccine in a subset of 9-12 months old infants" vide protocol no. BECT064TCVPhase-IV version 1.1 dated 20.09.21.

II. The firm is required Constitute a DSMB to review the safety data of Phase IV clinical trial.

III. The firm is required submit following data/documents:
   a. Copy of the Insurance Certificate.
   b. 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.

IV. 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.

V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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