

File No: BIO/CT/19/000098
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, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail: varma.bhupathiraju@biological.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.:BECT059/TCV-Pha-III, Version No. 1 Dated 09-SEP-2019** in the below mentioned clinical trial sites.

CT No.: CT- 02/2020

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.

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

Place: New Delhi
Date: 12-FEB-2020

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Typhoid Vi Conjugate Vaccine, IP	
Therapeutic class:	Vaccine	
Dosage form:	Solution for injection for Intramuscular injection	
Composition:	Each dose of 0.5 ml contains	
	Name of Active ingredient	Quantity
	Typhoid Vi Polysaccharide (<i>Citrobacter freundii sensu lato</i> 3056) conjugated to 16.7 µg – 100 µg of CRM ₁₉₇	25 µg
	Name of Inactive ingredients	Quantity
	Sodium dihydrogen phosphate dihydrate	0.475 mg
	Disodium hydrogen phosphate anhydrous	1 mg
	Sodium chloride	2.34 mg
	2-Phenoxyethanol (1.0 % w/v)	5 mg
	Water for injection I.P.	q.s.to 0.5mL
Indications:	For active immunization against infection caused by <i>Salmonella typhi</i> in infants, children, adolescents and adults aged ≥ 6 months to ≤ 45 years.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Jay Kay Ion Hospital attached to S.M.S. Medical College, J.L.N. Marg, Jaipur -302004, Rajasthan.	Ethics Committee, S.M.S. College and attached Hospitals, Jaipur, First Floor, Dhanvatari OPD Block, S.M.S. Hospital, J.L.N. Marg, Jaipur -302004, Rajasthan. ECR/26/Inst/RJ/2013/RR-19	Dr. Kapil Garg
2	Sant Dnyaneshwar Medical Education & Research Centre, Opp.: Vijay Cinema, Laxmi Road, Pune – 411030, Maharashtra.	Institutional Ethics Committee, Sant Dnyaneshwar Medical Education Research Centre, 695/A, Sadashiv Peth, Opposite Vijaya Talkies, Laxmi Road, Pune – 411030. ECR/127/Inst/MH/2013/RR-19	Dr. Asish Dhongade
3	Gandhi Medical College/ Hospital, Musheerabad, Secunderabad- 500003.	Institutional Ethics Committee, Gandhi Medical College/ Gandhi Hospital, Musheerabad, Secunderabad-500003, Telangana. ECR/180/Inst/AP/2013/RR-19	Dr. K. Siva Ram Prasad,
4	Pt. B. D. Sharma Post Graduate Institute of Medical Sciences, Directorate Office, Rohtak -124001.	Institutional Ethics Committee, Pt. B. D. Sharma Post Graduate Institute of Medical Sciences, Directorate Office, Rohtak-124001. ECR/293/Inst/HR/2013/RR-19	Dr. Savita Verma
5	Kalinga Institute of Medical Sciences, Kusha bhadra Campus (KIIT Campus -5),	Institutional Ethics Committee, Kalinga Institute of Medical Sciences, Kushabhadra Campus	Dr. Sonali Kar

	KIIT University, PO- KIIT, Patia, Bhubaneswar, Dist- Khurda, Odisha - 751024.	(KIIT Campus - 5), KIIT University, PO -KIIT, Patia, Bhubaneswar, Dist Khurda, Odisha – 751024. ECR/321/Inst/OR/2013/RR-16	
6	JSS Medical College & Hospital, Institutional Ethics Committee, JSS Medical College & Hospital, 3rd Floor, JSS Medical College, Mysore Karnataka – 570015.	Institutional Ethics Committee, JSS Medical College and Hospital, 3rd floor, JSS Medical College, Mysore-570015, Karnataka. ECR/387/Inst/KA/2013/RR-19	Dr. Mandyam Dhati Ravi
7	Guru Teg Bahadur Hospital, Dilshad Garden, North East Delhi – 110095.	Guru Teg Bahadur Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, North East Delhi –110095. ECR/510/Inst/DL/2014/RR-17	Dr. Manish Narang
8	Oriana Hospital, Plot No. 6,7,8, Ravindrapuri, Belupur, Varanasi –221005, Uttar Pradesh.	Ethics Committee, Oriana Hospital, Plot No. 6,7,8, Ravindrapuri, Belupur, Varanasi –221005, Uttar Pradesh. ECR/1003/Inst/UP/2017	Dr. Madhukar Pandey
9	Father Muller , Father Muller Ethics Committee, Father Muller Road, Kankanady, Mangalore Karnataka – 575002.	Institutional Ethics Committee, Father Muller Medical College, Father Muller Road, Kankanady, Mangalore - 5705002, Karnataka. ECR/540/Inst/KA/2014/RR-17	Dr. Pavan Hegde

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 multicentre follow-up study to assess the immunological persistence of anti-Vi IgG antibodies at 12, 24 and 36 months post primary dose and to evaluate the immune response to a single booster dose of typhoid Vi conjugate vaccine administered at 36 months post primary dose to 6 months to 45-year-old subjects in both treatment arms who participated in the BECT053 study, vide **Protocol no. BECT059/TCV-Pha-III, Version No. 1 Dated 09-SEP-2019**".
- II. To submit the 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 before initiation of subject trial.
- III. To submit the copy of Insurance Certificate (Certificate Only) before initiation of subject trial.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
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