

File No: BIO/CT/19/000065
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. V K Srinivas of M/s Bharat Biotech International Limited, Bharat Biotech International Limited Genome valley Shameerpet Mandal (India) – 500078 Telephone No.: 9848887849 FAX: 04023480560 E-Mail: vksrinivas@bharatbiotech to conduct clinical trial of the new drug or investigational new drug as per **protocol number: BBIL/TCV/IV-4/2019 Version No. 1.0** in the below mentioned clinical trial sites. dated **12-07-2019**.

CT No.: CT- 21/2019

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.

Place: New Delhi
Date: 30-SEP-2019

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

Digitally signed by V G SOMANI
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Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Typhoid Vi conjugate Vaccine
Therapeutic class:	Vaccine
Dosage form:	Liquid
Composition:	Purified Vi Capsular Polysaccharide of Salmonella typhi Ty2 conjugated to Tetanus Toxoid25.0000 micrograms (µg) I.P. Active Sodium Chloride.....4.5000 milligram (mg) I.P. Inactive Water for Injections.....0.5000 ml I.P. Inactive
Indications:	Active immunization against Typhoid fever caused by Salmonella Typhi Ty2

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, Maharanipecta, Visakhapatnam-530002.	Institutional Ethic Committee, King George Hospital, Maharanipecta, Visakhapatnam-530002. ECR/261/KGH/Inst/AP/2013/RR-16	Dr R Vasudev
2	PGME&R and SSKM hospital, A.J.C. Bose Road, Kolkata	Institutional Ethic Committee, PGME&R and SSKM hospital, A.J.C. Bose Road, Kolkata ECR/35/Inst/WB/2013/RR-16	Dr Anupam Mandal
3	Guru Teg Bahadur Hospital, Dilshad Garden, Delhi-110095	Guru Teg Bahadur Hospital Ethics committee, Dilshad Garden, Delhi-110095. ECR/510/Inst/DI/2014/RR-17	Dr Shiva Narang
4	Rahate Surgical Hospital, Near Telephone exchange square 517, Juni Mangalwari Central Avenue, Nagpur-440008	Institutional Ethic Committee, Rahate Surgical Hospital, Near Telephone exchange square 517, Juni Mangalwari Central Avenue, Nagpur-440008. ECR/601/Inst/MH/2014/RR-17	Dr Manish Multani
5	Prakhar Hospital, 8/219, Arya Nagar, Kanpur, UP-208002	Ethic Committee, Prakhar Hospital, 8/219, Arya Nagar, Kanpur, UP-208002. ECR/1017/Inst/UP/2017	Dr Jitendra Singh Kushwaha

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

- The clinical trial should be conducted as per approved protocol titled "A Phase IV Study to Evaluate the Immunogenicity and Safety of Purified Vi capsular polysaccharide (of Salmonella typhi, Ty2 strain) tetanus toxoid conjugate vaccine; Typbar -TCV® in Adults" vide protocol number: BBIL/TCV/IV-4/2019 Version No. 1.0 dated 12-07-2019.
- Only CDL, Kasauli certified batches shall be used in the clinical trial.

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