

File No: BIO/CT/19/000062
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. Mohammed Shafiqur Rahman of M/s Ra (Biologicals) Panacea Biotec Ltd., A-27, B-1 Extension Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044 Telephone No.: null FAX: null E-Mail:SHAFIQUURRAHMAN@PANACEABIOTEC.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: PBL/CR/19/01/TYCV Version No. 02 dated 28-09-19 in the below mentioned clinical trial sites.

CT No.: CT- 22/2019

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: 29-OCT-2019

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

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 Polysaccharide conjugated to Tetanus Toxoid25.0000 micrograms (µg) I.P. Active 2-phenoxyethanol.....2.5000 milligram (mg) I.P. Inactive Physiological Saline.....0.5000 ml I.P. Inactive
Indications:	Prevention of Typhoid disease caused by <i>Salmonella typhi</i>

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, Maharanipeta, Visakhapatnam-530 002.	Institutional Ethic Committee, King George Hospital, Maharanipeta, Visakhapatnam-530 002. ECR/197/Inst/KGH/2013/RR-16	Dr. R Vasudev
2	B.J. Govt. Medical College and Sasson General Hospital, Pune Station Road, Pune- 411 001, Maharashtra	Institutional Ethic Committee, B.J. Govt. Medical College and Sasson General Hospital, Department of Pharmacology, B.J. Govt. Medical College, Sasson Road, Pune- 411 001, Maharashtra ECR/280/Inst/MAHA-2016/RR-16	Dr. Harsal N. Bhitakar

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

- I. The clinical trial should be conducted as per approved protocol titled "An Open label, Single Arm, Non-Comparative Phase I Study to Evaluate the Safety and Immunogenicity of Typhoid (Vi Capsular polysaccharide) Tetanus Toxoid Conjugate Vaccine of Panacea Biotec Ltd. in healthy adults" vide protocol number: PBL/CR/19/01/TYCV Version No. 02 dated 28-09-19.
- II. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 29-OCT-2019

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