File No: BIO/CT/23/000112
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 Dr. V. Krishna Mohan, of M/s Bharat Biotech International Ltd., Sy. No. 230,231 & 235, Genome Valley, Turkapally, Shameerpet Mandal, Medchal - Malkagiri District, Telangana (India) - 500078 Telephone No.:04-023480567 FAX: 04023480560 E-Mail: info@bharatbiotech.com to conduct clinical trial of the new drug or investigational new drug as per [Protocol no. BBIL/TCV-III/2023; Version no. 02 dated 03.11.2023] in the below mentioned clinical trial sites.

**CT No.: CT- 04/2024**

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.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date:

**Annexure: Details of New Drug or Investigational New Drug:**

| | | |
|---|---|---|
| Name of the new drug or investigational new drug: | Typhoid Vi Conjugate Vaccine (Typhoid (Vi Capsular Polysaccharide) - Tetanus Toxoid Conjugate Vaccine) | |
| Therapeutic class: | Vaccine | |
| Dosage form: | Intramuscular injection | |
| Composition: | Each dose of 0.5 ml contains | |
| | **Name of Active ingredient** | **Quantity** |
| | Purified Vi Capsular Polysaccharide of S. typhi Ty2 conjugated to Tetanus Toxoid | 25.0000µg (I.H) |
| | **Name of Inactive ingredient** | **Quantity** |
| | 2-Phenoxyethanol (Preservative) | 5.0000 mg (B.P. / I.P.) |
| | Sodium Chloride | 4.500 mg (B.P. / I.P.) |
| | Water For Injection | Q.S to 0.5 mL (B.P. / I.P.) |
| Indication(s): | For active immunization against Salmonella typhi injection in Adults | |

**Details of clinical trial sites-**

| S. No. | Name and Address of Clinical Trial Site | Ethics Committee details | Name of Principal Investigator |
|---|---|---|---|
| 1 | Malla Reddy Narayana Multispecialty Hospital, Hyderabad | Malla Reddy Institute of Medical Sciences, Survey No.-138, Suraram Main Road, GHMC Quthbullapur, Jeedimetla, Hyderabad, Medchal–Malkajgiri, Telangana - 500055 ECR/828/Inst/AP/2016/RR-20 | Dr. Leelabati Toppo |
| 2 | Pt. P. D. Sharma Postgraduate Institute of Medical Sciences, PGIMS, Rohtak, Haryana | Pt. BD Sharma Post Graduate Institute of Sciences PGIMS UHS Rohtak, Haryana – 124001 ECR/293/Inst/HR/2013/RR-19 | Dr. Savita Verma |
| 3 | Redkar Hospital and Research Centre, Mumbai - Goa Highway, Dhargal, Dargalim, Oshalbag, Tal - Pernem, Goa 403513 | Redkar Hospital and Research Centre, Mumbai- Goa Highway, Oxelbag, Dhargal, Pernem, North Goa - 403513 ECR/902/Inst/GA/2018/RR-21 | Dr. Sagar Vivek Redkar |
| 4 | AIIMS, Patna Department of Community Medicine and Family Medicine, Aurangabad Road, Phulwari Sharif, Patna, Bihar-801507 | All India Institute of Medical Sciences, Patna, Phulwarisarif, Patna, Bihar – 801507 ECR/1387/Inst/BR/2020 | Dr. Chandramani Singh |

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 Phase III Open-label Study to Evaluate the Immunogenicity and Safety of Typhoid Tetanus Toxoid Conjugate Vaccine; Typbar TCV® in Adults (>65Years)” [Protocol no. BBIL/TCV-III/2023, Version no. 02 dated 03.11.2023.
II. The firm is required to constitute a DSMB to review the safety data.
III. Firm is required to submit Ethics Committee approval for Phase-III clinical trial.
IV. The formulation intended to be used in the clinical trial shall be manufactured and validated under GMP conditions.

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

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