File No: BIO/CT/24/000013
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 Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Tal.: Sanand, Dist.: Ahmedabad – 382213, State: Gujarat, (India), Telephone No. 91-2717-664600, Fax: 91-2717-664600, E-Mail: sanjaymaheshwari@zyduslife.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: BTPT 1001, Version No. 02 dated 16th May 2024 in the below mentioned clinical trial sites.

CT No.: CT- 07/2024

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:

<table>
<tr><td>Name of the new drug or investigational new drug</td><td>Bivalent Typhoid and Paratyphoid A Conjugate Vaccine</td></tr>
<tr><td>Therapeutic class</td><td>Vaccine</td></tr>
<tr><td>Dosage form</td><td>Intramuscular Injection 0.5 mL</td></tr>
<tr><td>Composition</td><td>Each dose of 0.5 mL contains:
<table>
<tr><th>Name of Active Ingredients</th><th>Quantity</th></tr>
<tr><td>Purified Vi capsular polysaccharide of S. typhi conjugated to 16-50 µg of Tetanus toxoid (Carrier protein)</td><td>25 µg</td></tr>
<tr><td>Purified OS polysaccharide of S. Paratyphoid A conjugated to 16-50 µg of Diphtheria toxoid (Carrier protein)</td><td>25 µg</td></tr>
<tr><th>Inactive Ingredients</th><th>Quantity</th></tr>
<tr><td>2- Phenoxyethanol</td><td>2.5 mg</td></tr>
<tr><td>Normal Saline</td><td>q.s. to 0.5 mL</td></tr>
</table></td></tr>
<tr><td>Indication(s):</td><td>Active immunization for prevention of Typhoid Fever and Paratyphoid A Fever.</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Zydus Research Centre, Zydus Lifesciences Ltd., Survey No. 396/403, Opp. Sarvotam Hotel, Nr. Nova Petrochemicals, Sarkhej - Bavla, N. H. No. 8A, Village: Moraiya, Ahmedabad – 382213, Gujarat, India.	Riddhi Medical Nursing Home Institutional Ethics Committee, Riddhi Medical Nursing Home, A/101 Jalaram Plaza Jawahar Chowk, Maninagar, Ahmedabad, Gujarat – 380008, India. [ECR/886/Inst/GJ/2016/RR-19]	Dr. Krunal Prajapati

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

I. The Phase-I clinical trial should be conducted as per approved protocol titled “An open-label, single-treatment, single-period, single dose, clinical phase 1 study to assess the safety and tolerability of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine (BTPT) of M/s Zydus Lifesciences Ltd., India in healthy, adult human subjects” vide [Protocol No.: BTPT 1001 Version No. 02 Dated 16th May 2024].
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-I clinical trial.
IV. The formulation intended to be used in clinical trial shall be manufactured under GMP conditions.
V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
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Place: New Delhi
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