File No: BIO/CT/25/000046
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

The Drugs Controller General, India
Directorate General of Health Services,

To

M/s Human Biologicals Institute
(A division of Indian Immunologicals Limited),
Rakshapuram, Gachibowli, Telangana (India) – 500032

Subject: Permission for conducting a clinical trial titled "An open label phase I study to evaluate the safety and immunogenicity of Typhoid Bivalent Conjugate Vaccine of HBI when administered to healthy male subjects of 18 to 50 years of age" [Protocol number: HBI/Typ1/25/01.1.1, Version: 01; Amendment: 01 Dated: 23 July 2025] – regarding.

Reference: Your Application No. BIO/CT04/FF/2025/48626 dated 28-Mar-2025 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2025/48626 dated 28-MAR-2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Typhoid Bivalent Conjugate Vaccine" in Single dose (0.5mL) & Multidose (2.5mL) vial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.10.31 18:09:24 +05'30'

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

File No: BIO/CT/25/000046
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 Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Telangana (India) – 500032, Telephone No. 91-9948298622, FAX: 91-9948298522 to conduct clinical trial of the new drug or investigational new drug as per Protocol number: HBI/Typ1/25/01.1.1, Version: 01; Amendment: 01 Dated: 23 July 2025.

CT No.: CT- 21/2025

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.

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Date: 2025.10.31 18:09:38 +05'30'

(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>Typhoid Bivalent Conjugate Vaccine</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Injectable (Intramuscular), Sterile liquid in USP type 1 glass vials</td></tr>
<tr><td>Composition:</td><td>Composition for Single Dose (0.5mL):
Each 0.5mL contains:
<table>
<tr><th>Component</th><th>Concentration/0.5mL</th></tr>
<tr><td colspan="2">Active Ingredients</td></tr>
<tr><td>Purified Vi-Capsular Polysaccharide of S. typhi Ty2 conjugated to Tetanus Toxoid</td><td>≥ 25µg</td></tr>
<tr><td>Purified O-specific polysaccharide of S. paratyphi A conjugated to Tetanus Toxoid</td><td>≥ 25µg</td></tr>
<tr><td colspan="2">Inactive Ingredients</td></tr>
<tr><td>Phosphate Buffer Saline-IH</td><td>q.s. to 0.5mL</td></tr>
</table>
Composition for Multi Dose (2.5mL)
Each 0.5mL contains:
<table>
<tr><th>Component</th><th>Concentration/0.5mL</th></tr>
<tr><td colspan="2">Active Ingredients</td></tr>
<tr><td>Purified Vi-Capsular Polysaccharide of S.typhi Ty2 conjugated to Tetanus Toxoid</td><td>≥ 25µg</td></tr>
<tr><td>Purified O-specific polysaccharide of S.paratyphi A conjugated to Tetanus Toxoid</td><td>≥ 25µg</td></tr>
<tr><td colspan="2">Inactive Ingredients</td></tr>
<tr><td>2-Phenoxyethanol I.P.</td><td>2.5mg</td></tr>
<tr><td>Phosphate buffer saline IH</td><td>q.s. to 0.5mL</td></tr>
</table></td></tr>
<tr><td>Indication(s):</td><td>Primary Prevention of Typhoid and Paratyphoid infections.</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	Department of Community and Family Medicine, All India Institute of Medical Sciences, Virbhadra Road, Rishikesh, Uttarakhand – 249203, India.	Ethics Committee relating to Clinical Trial, All India Institute of Medical Sciences, Virbhadra Marg, Rishikesh Uttarakhand – 249203, India. EC registration No: ECR/736/Inst/UK/2015/RR-21	Dr. Mahendra Singh

In addition to point 3, the permission is subject to following condition(s):

I. The Phase I clinical trial should be conducted as per title "An open label Phase I study to evaluate the safety and immunogenicity of Typhoid bivalent conjugate vaccine of HBI when administered to healthy male subjects of 18 to 50 years of age" [Protocol Number: HBI/Typ1/25/01.1.1, Version: 01; Amendment: 01; Dated: 23 July 2025].
II. The firm is required to constitute a DSMB to review the safety data.
III. The formulation intended to be used in the clinical trial shall be manufactured under GMP Conditions.
IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.
V. To submit Ethics Committee approval for Phase-I clinical trial.
VI. To submit CRO registration details once obtained from the CDSCO.

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

Place: New Delhi
Date: