File No: BIO/CT/23/000154
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/Td3/23/03.2.0, Version No.: 2.0 dated 24.03.2025 in the below mentioned clinical trial sites.

CT No.: CT- 12/2025

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.

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>Diphtheria and Tetanus Vaccine (Adsorbed) for Adults & Adolescents I.P.</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Suspension for intramuscular injection</td></tr>
<tr><td>Composition:</td><td>Each single human dose of 0.5mL contains:
<table>
<tr><th>Ingredients</th><th>Quantity</th></tr>
<tr><td>Diphtheria Toxoid
Corynebacterium diphtheriae CN 2000
(Sub-strain of PW 8 strain)</td><td>≥ 2 IU (≤5 Lf)</td></tr>
<tr><td>Tetanus Toxoid
Clostridium tetani No: 49205 Harvard strain</td><td>≥ 20 IU (≥5 Lf)</td></tr>
<tr><td>Aluminum Phosphate as Al^{+++}</td><td>≤ 1.25 mg</td></tr>
<tr><td>Thiomersal</td><td>0.01 % w/v</td></tr>
<tr><td>Saline</td><td>q.s. to 0.5 mL</td></tr>
</table></td></tr>
<tr><td>Indication(s):</td><td>Prevention of Diphtheria and Tetanus in Pregnant women and in the newborn infants.</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and address of clinical trial sites	Ethics Committee details	Name of Principal Investigators
1.	Department of Gynecology, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan – 305001. [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Suchitra Narayan
2.	Department of Obstetrics & Gynaecology, SN Medical College, Near Central Library, Moti Katra, Mantola, Agra, Uttar Pradesh-282003, India.	Institutional Ethics Committee S.N Medical College, Raja Mandi, Near Agra Central Library, Moti Katra, Mantola, Agra, Uttar Pradesh – 282003. [ECR/1409/Inst/UP/2020]	Dr. Ruchika Garg
3.	Department of Obstetrics and Gynecology, St. Theresa's Hospital Ground floor, Sanath Nagar, Hyderabad- 500018. Telangana, India.	Ethics Committee, St. Theresa's Hospital, Sanathnagar, Opp. Erragadda Raitu Bazar, Hyderabad, Telangana – 500018. [ECR/230/Inst/AP/2013/RR-22]	Dr. Badami Aruna
4.	Dept of Community Medicine & Family Medicine, AIIMS, Sijua, Patrapada, Bhubaneswar-751019, Odisa, India.	Institutional Ethics Committee, Faculty Research, AIIMS Bhubaneswar, All India Institute of Medical Sciences, BBSR, AIIMS Bhubaneswar, Sijua, P/O	Dr. Swayam Pragyan Parida

		Patrapada, Bhubaneswar, Khordha, Orissa – 751019 India. [ECR/534/Inst/OD/2014/RR-25]	

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

1. The Phase-III clinical trial should be conducted as per approved protocol titled “An open label multicentric clinical trial to evaluate the safety and immunogenicity of Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents I.P. (TeddyVac™ vaccine) in healthy pregnant women.” vide Protocol no. HBI/Td3/23/03.2.0, Version No.: 2.0 dated 24.03.2025.
2. To submit Ethics Committee approvals and Insurance certificates for said Phase III clinical.
3. Only CDL, Kasauli certified vaccines already approved for manufacturing & marketing shall be used in Phase-III clinical trial in healthy pregnant women in India.

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