File No: BIO/CT/23/000129
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 phase III clinical trial titled "An open label multicentric clinical trial to evaluate the safety and immunogenicity of Tetanus vaccine (Adsorbed) I.P. (AbhayTOX® vaccine) in healthy pregnant women". Protocol No: HBI/TOX4/23/02.2.0 Version: 02; Dated: 20 January 2025- regarding.

Reference: Your Application No BIO/CT04/FF/2023/39995 dated 14-OCT-2023 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2023/39995 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct a Phase III clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs and Cosmetics Rules, 1945 and communication of Central Licencing Authority.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.06.20 17:58:31 +05'30'

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

File No: BIO/CT/23/000129

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 grant permission to 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 No.: HBI/TOX4/23/02.2.0, Version: 02; Dated: 20 January 2025 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT- 13 /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: 2025.06.20 17:57:57 +05'30'

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

Place: New Delhi
Date

File No: BIO/CT/23/000129

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Tetanus Vaccine (Adsorbed) I. P.	
Therapeutic class:	Vaccine	
Dosage form:	Vaccines (Liquid),0.5 mL (single dose presentation) in USP type 1 ampoules and 5 mL (multidose presentation) in USP type 1 tubular glass vials	
Composition:	**Each dose of 0.5 mL Vaccine contains:**	
	Composition	**Quantity**
	Active Ingredients	
	Tetanus Toxoid I.P.	≥ 40 IU (5 to 25 Lf)
	Inactive ingredients	**Quantity**
	Al^{+++}(As $AlPO_4$) I.H.S.	≤ 1.25 mg
	Thiomersal I.P.	0.01 % w/v
	Saline I.H.S.	q.s. to 0.5 mL
Indication	Active immunization against tetanus	

Details of clinical trial sites-

S.No.	Names and Address of Clinical Trial Site	Ethics Committee Details	Name of Investigator(s) & Designation
1.	Maharaja Agrasen Superspeciality Hospital, Central Spine , Agrasen Aspatal Marg Sector 7, Vidhyadhar Nagar, Jaipur Rajasthan - 302039	IEC Maharaja Agrasen Hospital, Maharaja Agrasen Super Speciality Hospital, Central Spine, Agrasen aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur- 302039, Rajasthan, India. [ECR/1222/Inst/RJ/2019/RR-22]	Dr.Madhavendar Jain
2.	Acharya Vinoba Bhave Rural Hospital, Sawangi (M), Wardha - 442004, Maharashtra, India.	Institutional Ethics Committee, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe), Wardha, Maharashtra-442004, India [ECR/440/Inst/MH/2013/RR-24]	Dr Neema Acharya
3.	Baramati Hospital Pvt. Ltd., Behind Kavivarya Moropant Natyamandir, New Indapur Ring Road, Baramati - 413102,Maharashtra, India.	Ethic Committee of Baramati Hospital Pvt. Ltd., Behind Kavivarya Moropant Natyamandir, New Indapur Ring Road, Baramati - 413102,Maharashtra, India. [ECR/1449/Inst/MH/2020]	Dr Vibhavari Shrirang Solunke

4.	Health 1 Super Speciality Hospital, Near Venitian Villa,Shilaj Circle, S.P. Ring Rd, Thaltej, Ahmedabad-380059, Gujarat, India	Health 1 Super Speciality Hospital EC, Health 1 Super Speciality Hospital Block C,GF To 8 Floor, Shilaj 23/73, On S.P. Ring Road, Near Shilaj Circle, Shilaj, Ahmedabad, Gujarat -380059, India [ECR/1666/Inst/GJ/2022]	Dr Samir Anilkumar Thakkar

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

1. The clinical trial should be conducted as per approved protocol titled " An open label multicentric clinical trial to evaluate the safety and immunogenicity of Tetanus vaccine (Adsorbed) I.P. (AbhayTOX® vaccine) in healthy pregnant women with Protocol No: HBI/TOX4/23/02.2.0 Version: 02; Dated: 20 January 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 said Phase III clinical trial in healthy pregnant women in India.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date