File No: BIO/CT/20/000149
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 Licensing Authority hereby permits M/s Indian Immunological Limited, Rakshapuram, Gachibowli post Hyderabad Rangareddi Hyderabad-500032, India, Telephone No.: 04023000211, FAX no.: 04023000512, E-mail: ankur.namdeo@indimmune.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: HBI/Td/II/III/2020/002.01.01 Dated: 05 April 2021** in the below mentioned clinical trial sites.

CT No.: CT- 16/2021

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.

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: 02-JUNE-2020

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents IP
Therapeutic class:	Vaccine
Dosage form:	Suspension for Injection
Composition:	Each dose of 0.5 ml contains:

Name of Active ingredient	Quantity
Diphtheria Toxoid	≥ 2 IU (≤ 5 Lf)
Tetanus Toxoid	≥ 20 IU (≥ 5 Lf)
Aluminium Phosphate as Al+++	≤ 1.25 mg
Thiomersal (as preservative)	0.01 % w/v
Saline	q.s.to 0.5 ml

Indications:	Prophylaxis against Diphtheria and Tetanus in Adults and Adolescents in age group of 10 years to 60 years of age.

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	MCH Block, Guru Teg Bahadur Hospital, Dilshad Garden Delhi 110095,India	Institutional Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden Delhi 110095,India ECR/510/Inst/DL/2014/RR-20	Dr. Manish Narang
2	Pulse Multispecialty Hospital, Narhe,Pune-41104, Maharashtra	Ethics Committee of Pulse Multispecialty Hospital, Narhe,Pune-41104, Maharashtra, ECR/1339/Inst/MH/2020	Dr. Prashant Namdev Khandgave
3	IMS & SUM Hospital, Siksha 'O' Anusandhan deemed to be University, Kalinga Nagar, Bhubaneswar-751003 Odisha,	Institutional Ethics Committee, IMS & SUM Hospital, Siksha 'O' Anusandhan deemed to be University, Kalinga Nagar, Bhubaneswar-751003 Odisha, ECR/627/Inst/OR/2014/RR-20	Dr. Lipilekha Patnaik
4	King George Hospital, Visakhapatnam –530002Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital, Visakhapatnam –530002Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR-20	Dr. Vasudev Rajapantula

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 II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of Diphtheria and Tetanus vaccine (Adsorbed) for Adults and Adolescents (Td vaccine) of HBI with BE Td® Vaccine in two age groups of Healthy Subjects". Protocol no.: HBI/Td/II/III/2020/002.01.01 Dated: 05 April 2021.
II. DSMB shall be constituted for assessment of safety.

III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.

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

Place: New Delhi
Date: 02-JUNE-2021

(Dr. V. G. Somani)
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