

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR
INVESTIGATIONAL NEW DRUG

File No. : BIO/CT/20/000149

The Central Licencing Authority hereby permits Dr. Anand Kumar K of M/s Indian Immunological Limited, RAKSHAPURAM GACHIBOWLI POST HYDERABAD RANGAREDDI HYDERABAD (India) - 500032 Telephone No.: 04023000211 FAX: 04023000512 E-Mail : MSRS@INDIMMUNE.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: HBI/Td/II/III/2020/2 Version No. 01 Protocol Date 22-JUL-2020 in the below mentioned clinical trial sites.

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

Names of the new drug or	Therapeutic class:	Dosage form:	Composition:	Indications:
Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.	Vaccine	Vaccines (Liquid)	Saline ≤ 0.5000 ml In House Specification Inactive Thiomersal (as preservative) $= 0.0100$ % w/v I.P. Inactive Aluminium Phosphate as $Al^{+++} \leq 1.2500$ milligram (mg) In House Specification Inactive Tetanus toxoid ≥ 20.0000 IU I.P. Active Diphtheria Toxoid ≥ 2.0000 IU I.P. Active	Prophylaxis against Diphtheria and Tetanus in Adults and Adolescents

S.No.	Names and address of clinical trial site	Ethics committee details:	Name of Principal Investigator
1	King George Hospital , institutional Ethics committee King George Hospital Visakhapatnam Andhra Pradesh - 530002	IEC King George hospital	Dr YG Sundar Raju
2	Gur Teg Bahadur Hospital , Gur Teg Bahadur Hospital Ethics Comittee (GTBHEC) Situated at Dilshad Garden, Shadhra, New Delhi Delhi - 110095	Guru Teg Bahadur Hospital Ethics Committee	Dr Manish Narang
3	Institute of Medical Sciences (IMS) and SUM Hospital, Ethics Committee, Institute of Medical Sciences (IMS) and SUM Hospital, S 'O' A University, K8, Kalinga Nagar, Bhubaneswar Orissa - 751003	IEC IMS and SUM Hospital	Dr Lipilekha Patnaik

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.

Place :

Central Licencing Authority
Stamp

Date : 02-JUN-2021

