

File No: BIO/CT/22/000022  
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 Panacea Biotec Ltd., B-1 Extn/G-3, MCIE Mathura Road New Delhi New Delhi (India) - 110044 Telephone No.: 01141679045 FAX: 01141679063 E-Mail : [shafiqurrahman@panaceabiotec.com](mailto:shafiqurrahman@panaceabiotec.com) to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: PBL/21/01/Td Version Number: 03** **Dated: 04-10-22** in the below mentioned clinical trial sites.

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| <b>CT No.: CT- 24/2022</b> |
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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.
4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Place: New Delhi  
Date: 26 -OCT-2022

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

**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 I.P. (Td Vaccine) |                 |
| Therapeutic class:                                | Vaccine                                                                                |                 |
| Dosage form:                                      | Suspension for injection for intramuscular route of administration                     |                 |
| Composition:                                      | Each dose of 0.5 ml vaccine contains:                                                  |                 |
|                                                   | <b>Name of ingredient</b>                                                              | <b>Quantity</b> |
|                                                   | Diphtheria Toxoid                                                                      | NLT 2 IU        |
|                                                   | Tetanus Toxoid                                                                         | NLT 20 IU       |
|                                                   | 2-Phenoxyethanol                                                                       | 2.5 mg          |
|                                                   | Aluminium Phosphate Gel                                                                | NMT 1.25 mg     |
|                                                   | Physiological Saline                                                                   | q.s. to 0.5 ml  |
| Indications:                                      | for active immunization for the prevention of tetanus and diphtheria                   |                 |

**Details of clinical trial sites-**

| S. No | Name and Address of Clinical Trial Site                                                                     | Ethics Committee details                                                                                                                                                       | Name of Principal Investigator |
|-------|-------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 1     | All India Institute Of Medical Sciences, Patna Phulwarisharif, Patna, Bihar -801507 India                   | EC-AIIMS All India Institute Of Medical Sciences, Patna Phulwarisharif, Patna, Bihar - 801507 India<br>ECR/1387/Inst/BR/2020                                                   | Dr. Chandramani Singh          |
| 2     | Rana Hospital Pvt. Ltd, Rail Vihar Medical College Road Chargawan Gorakhpur Uttar Pradesh -273001 India     | Institutional Ethics Committee Rana Hospital Rana Hospital Pvt. Ltd, Rail Vihar Medical College Road Chargawan Gorakhpur Uttar Pradesh -273001 India.<br>ECR/1332/Inst/UP/2020 | Dr Ajeet Pratap Singh          |
| 3     | Niloufer Hospital, Red Hills, Lakdi ka pool, Hyderabad-500004, Telangana, India                             | Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500059, Telangana<br>ECR/300/Inst/AP/2013/RR-19                                                       | Dr N. Ravi Kumar               |
| 4     | Jeevan Rekha Hospital, Dr B. R. Ambedkar Road, Belagavi-590002, Karnataka, India                            | Institutional Ethics Committee, Jeevan Rekha Hospital, Dr B. R. Ambedkar Road, Belagavi-590002, Karnataka.<br>ECR/1242/Inst/KA/2019                                            | Dr Amit Suresh Bhate           |
| 5     | IMS and SUM Hospital IMS and SUM Hospital K8 kalinganagar shampur Bhubaneswar, Khordha Orissa -751003 India | EC IMS and SUM Hospital IMS and SUM Hospital K8 kalinganagar shampur bhubaneswar Khordha Orissa - 751003 India.<br>ECR/627/Inst/OR/2014/RR-20                                  | Dr Braja Kishore Behera        |
| 6     | Prakhar Hospital Pvt. Ltd., 8/219, Arya nagar, Kanpur 208008 UP.                                            | IEC Prakhar Hospital Pvt. Ltd., 8/219, Arya nagar, Kanpur 208008 UP.<br>ECR/1017/INST/UP/2017/RR-21                                                                            | Dr. Jitendra Singh Kushwaha    |

In addition to point 4, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled "A randomized, single blind, multicenter, Phase II/ III study to assess and compare the immunogenicity and safety of Diphtheria and Tetanus (Td) vaccine (adsorbed) of Panacea Biotec Ltd. with BE Td® of M/s. Biological E Ltd in Healthy Adults & Adolescents." Protocol Number: PBL/21/01/Td Version Number: 03 Dated: 04-10-22.
- 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.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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