File No: BIO/CT/23/000032
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 Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com, to conduct Phase I clinical trial of the new drug or investigational new drug as per Protocol No: BBIL/BBV169-I/2023 Version No: 4.0; Date: 31 Oct. 2023 in the below mentioned clinical trial sites.

CT No.: CT- 16/2023

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:

Name of the new drug or investigational new drug:	Mycobacterium Tuberculosis (Live, Attenuated) Vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized Vaccine (10 dose vial) (Intradermal)	
Composition:	After reconstitution with 1.0 mL sterile water for injection, each 0.1 ml dose of Vaccine contains:	
	Ingredients	**Quantity**
	Mycobacterium tuberculosis MTBVAC01 Strain	5×10^5 CFU
	Sucrose	3.3-13.3%
	Monosodium Glutamate	0.33-1.33%
Indications:	For active immunization against Tuberculosis	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Department of Clinical Pharmacology & Therapeutics, Nizam Institute of Medical Sciences, Hyderabad, Telangana	Institutional Ethics Committee, NIZAMs Institute of Medical Science, Punjagutta, Hyderabad, Telangana - 500082. [ECR/303/Inst/AP/2013/RR-19]	Dr. Chinthaparthi Prabhakar Reddy

In addition to point 3, the permission is subject to following condition(s):

I. The Phase I clinical trial should be conducted as per title "Protocol Title: An Open Labelled Phase I Clinical Trial to Assess the Safety, Reactogenicity, Tolerability and Immunogenicity of a Tuberculosis Vaccine BBV169 (MTBVAC), in Healthy Indian Adults"; (Protocol no. BBIL/BBV169-I/2023 Version-4.0; Date: 31-Oct-2023.
II. The firm is required to constitute a DSMB to review the safety data.
III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
IV. GMP Certificate (in English language) of the manufacturing site shall be submitted where the clinical batches have been manufactured.
V. COA of three batches along with CDL report shall be submitted.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.
VII. Firm is required to submit Ethics Committee approval for clinical trial
VIII. Firm shall submit separate application for Phase-II protocol in line with recommendations of SEC Vaccine dated 31.10.2023.

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Date: 2024.01.01 10:55:18 +05'30'

Place: New Delhi
Date:

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