File No: BIO/CT/24/000042
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 Dr. V. Krishna Mohan of M/s Bharat Biotech International Limited, Sy. No. 230, 231& 235, Genome Valley, Turkapally, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana (India) – 500078, Telephone No.:04045464537, FAX: 04023480560, E-Mail: dra@bharatbiotech.com to conduct Phase-II clinical trial of the new drug or investigational new drug as per [Protocol no. BBIL/MTBVAC-II/2024; Version no. 2.0 dated 30.04.2024] in the below mentioned clinical trial sites.

CT No.: CT- 05/2024

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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(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 0.1mL dose of Vaccine contains:	
	Ingredients	**Quantity**
	Active ingredient	
	Mycobacterium tuberculosis MTBVAC01 Strain	5 X 10^5 CFU
	Inactive ingredients	
	Sucrose	3.3 to 13.3%
	Monosodium Glutamate	0.33 to 1.33%
Indication(s):	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 Centre for Community Medicine, AIIMS, Ansari Nagar East, New Delhi -110029	Institute Ethics Committee, All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-29 [ECR/538/Inst/DL/2014/RR-20]	Dr. Sanjay Kumar Rai
2	Department of Medicine, Guru Teg Bahadur Hospital, Dilshad Garden, Delhi-110095	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, Delhi- 110095 [ECR/510/Inst/DL/2014/RR-20]	Dr. Shiva Narang
3	Department of Clinical Pharmacology & Therapeutics, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad, Telangana-500082	NIMS Institutional Ethics Committee, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad, Telangana-500082 [ECR/303/Inst/AP/2013/RR-19]	Dr. Prabhakar Reddy
4	Department of Pulmonary Medicine, Rajarajeswari Medical College and Hospital, Kambipura, Mysore Road, Bangalore-560074	Institutional Ethics Committee, Rajarajeswari Medical College and Hospital, No. 202, Kambipura, Mysore Road, Bengaluru (Bangalore), Karnataka -560074 [ECR/1458/Inst/KA/2024]	Dr. Vinod Kolla

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 Randomized, Double-blind Trial to Access the Safety and Immunogenicity of MTBVAC (BBV169), with BCG vaccine as a comparator in Healthy adolescent and adult populations” [Protocol no. BBIL/MTBVAC-II/2024, Version no. 2.0 dated 30.04.2024].
II. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
III. Only CDL, Kasauli certified batches shall be used in Phase-II clinical trial.
IV. To submit label of Investigational product to be used in Phase-II clinical trial.
V. To submit Ethics Committee approval for Phase-II clinical trial.
VI. To submit DSMB report of 90 days & 180 days post vaccination as per protocol for completed Phase-I clinical trial.

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

Place: New Delhi
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