

File No: BIO/CT/20/000049

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 Haffkine Institute For Training, Research & Testing ,Acharya Donde Marg Parel Mumbai (India) - 400012, Telephone No.: 022-24160947 FAX: 022-24161787 E-Mail : director@haffkineinstitute.org to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: 1.0** in the below mentioned clinical trial sites.

CT No.: CT- 10/2020

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.

Place: New Delhi

(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:	Bacillus Calmette-Guerin Vaccine I.P. (Freeze Dried)	
Therapeutic class:	Vaccine	
Dosage form:	Freeze dried powder for Injection	
Composition:	Each 1 ml Live attenuated Bacillus Calmette-Guerin Vaccine I.P. (Freeze Dried) contains:	
	Name of ingredients	Quantity
	BCG (bacterial suspension),IP/BP/EP	2x10 ⁶ to 8x10 ⁶ CFU
	Name of ingredients	Quantity
	Sodium Glutamate , USP	7.5 mg
	Diluent [Sodium Chloride Injection 0.9% w/v (1 ml)]	
	Sodium Chloride	9 mg / ml
	Water for Injection I.P.	q.s.
Indications:	For potential therapy for COVID-19	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	B. J. Govt. Medical College & Sassoon General Hospital, Jayprakash Narayan Road, Near Pune Railway Station, Pune 411001	Institutional Ethics Committee, B. J. Govt. Medical College & Sassoon General Hospital, Jayprakash Narayan Road, Near Pune Railway Station, Pune 411001 ECR/280/Inst/Maha/2013/RR-19	Dr. Sonali Salvi

The clinical trial should be conducted as per protocol no. 1.0 titled "Phase 2 Clinical Trial for the Evaluation of BCG as potential therapy for COVID-19" subject to the following conditions:

1. The study should be carried out only in moderate patients. Accordingly the objective criteria for classifying moderate patients should be defined.
2. The primary objective should be the time for resolution of COVID-19 infection only. All other objectives should be secondary objectives. Progression from moderate to severe disease should also be a secondary objective.

Accordingly, the revised protocol should be submitted to this office before initiation of the clinical trial along with ethics committee approval and copy of the insurance certificate.

Place: New Delhi

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