File No: BIO/CT/21/000079

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 clinical trial of the new drug or investigational new drug as per Protocol BBIL/BBV151/2021, version no. 1.0 dated 05-06-2021 in the below mentioned clinical trial sites.

CT No.: CT- 21/2021

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.

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2021.07.09 15:41:55 +05'30'

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

Place: New Delhi
Date: 09.07.2021

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Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Coronavirus vaccine (rDNA) – BBV151		
Therapeutic class:	Vaccine		
Dosage form:	Liquid injection for intramuscular route Strength: NLT 30µg/SHD (0.5mL) and NLT 15µg/SHD (0.25mL)		
Composition:	Each dose of 0.5 ml contains:		
	Component (A)	**Active ingredient:**	**Quantity**
		Purified, BPL Inactivated Corona virus (rDNA) Antigen	NLT 30 mcg
		Inactive ingredients:	
		Phosphate Buffered Saline	Q.s. to 0.25 ml
	Component (B)	**Adjuvant:**	**Quantity**
		SEPIVAC SWE - Oil in water (O/W)emulsion*	0.25 ml
	*Squalene based Oil in Water emulsion		
	Presentation 1: Component A and B will be provided in two separate vials and will be mixed at the time of administration. Presentation 2: Component A and B will be mixed together, before itself and will be provided in single vial (0.5 ml dose volume)		
Indications:	For active immunization against Corona Virus Infections (SARS-CoV-2) COVID-19.		

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Shree Hospital Unit, Plot No. 786A, Behind Shree Hospital & Critical Care Center, Mirchi Bazar, Sakkardara Sq, Nagpur - 440 009, Maharashtra	Shree Hospital Ethics Committee Shree Hospital Unit, Plot No.786 A, 3d Floor Behind Shree Hospital & Critical Care Centre, Mirchi Bazaar, Umrer Road, Sakkardara, Sq, Nagpur-440009,Maharashtra, India ECR/553/Inst/MH/2014/RR-20	Dr Akash Balki
2	Jeevan Rekha Hospital, Dr. B. R Ambedkar Road, Belagavi – 590 002.	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B R Ambedkar Road, Belagavi - 590002, ECR/1242/Inst/KA/2019	Dr Suresh G Bhate
3	All India Institute of Medical Science, Patna, Bihar - 801 507	Institutional Ethics Committee, All India Institute of Medical Science, Patna, Bihar - 801 507 ECR/1387/Inst/BR/2020	Dr Sanjay Pandey

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

I. The Phase I clinical trial should be conducted as per protocol titled “A Phase I, Open label, Dose escalation, Randomized, Multicenter Study to Evaluate the Reactogenicity, Safety, and Immunogenicity of an Intramuscular inactivated rabies vector platform Corona Virus Vaccine (rDNA-BBV151) in Healthy Volunteers” vide protocol no. BBIL/BBV151/2021, version no. 1.0 dated 05-06-2021.
II. The firm is required to constitute a DSMB to review the safety data.
III. Firm is required to submit copy of the Insurance Certificate.
IV. Firm is required to submit copy of details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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Place: New Delhi
Date: 09.07.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
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