File No: BIO/CT/20/000078

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 No.: BBIL/BBV152D-B/2020 Version No: 2.0 Date: 27-07-2020** in the below mentioned clinical trial sites.

CT No.: CT- 20/2020

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.

VENUGOPAL GIRDHARILAL SOMANI

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

Place: New Delhi
Date: 20/08/2020

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Whole Virion Inactivated Corona Virus Vaccine, [BBV152D]	
Therapeutic class:	Vaccine	
Dosage form:	Liquid Injection (Intradermal route)	
Composition:	Each dose of 0.1 ml contains	
	Active ingredient	**Quantity**
	Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770	1.20 mcg
	Inactive ingredients	
	2-Phenoxyethanol (2PE) I.P.	0.5 mg
	Phosphate Buffered Saline	Qs to 0.1 ml
Indications:	For active immunization against Corona Virus Disease (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	ESI Hospital, Sanathnagar, Hyderabad, Telanagana	Institutional Ethics Committee ESIC Medical College and Hospital, Sanath Nagar Hyderabad Telangana - 500038 ECR/1303/Inst/TG/2019	Dr. Rajiv Bandaru
2	PGIMS, Rohtak, Haryana	Institutional Ethics committee, PGIMS, Rohtak, Haryana ECR/293/Inst/HR/2013/RR-19	Dr. Savita Verma
3	Meditrina Institute of Medical Sciences, Nagpur, Maharashtra 440010	Ethics committee, Meditrina Institute of Medical Sciences, Nagpur, Maharashtra 440010 ECR/608/INST/MH/2014/RR-17	Dr. Atul Rajkondawar
4	Sri Ramachandra Medical College and Research Institute, Chennai, Tamilnadu 600116	Institutional Ethics committee, Sri Ramachandra Medical College and Research Institute, Chennai, Tamilnadu 600116 ECR/203/Inst/TN/2013/RR-19	Dr. R. B. Sugagar Singh
5	St. Theresa Hospital, Erragadda, Hyderabad, Telanagana 500018	Ethics committee, St. Theresa Hospital, Erragadda, Hyderabad, Telanagana 500018 ECR/230/Inst/AP/2013/RR-16	Dr. A V Rao

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

I. The Phase I/II clinical trial should be conducted as per protocol titled " An Adaptive, Seamless Phase I, Followed by a Phase II, Randomized, Multicenter Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of the Whole Virion Inactivated SARS-CoV-2 Virus Vaccine, BBV152D Administered Intradermally in Healthy Volunteers" vide Protocol No: BBIL/BBV152D-B/2020 Version No: 2.0 Date: 27-07-2020.

II. Firm is required to submit following information/documents & initiate the trial on satisfactory results:
   a) Detailed manufacturing process along with details of developmental batches for BBV152 (A, B, C & D formulations) including composition, site, scale, stability etc.
   b) To include other stability indicating parameters in future batches as per WHO TRS on stability guidelines.
   c) Ongoing and updated animal studies report of animal toxicity data with ID route in Balb/C mice, Wistar Rats & New Zealand Rabbits.
   d) Insurance Certificate before initiation of trial
   e) Details of the contract entered by the sponsor with the investigator/institutions for remaining clinical trial sites.

III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.

IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)
Drugs Controller General (India)
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Place: New Delhi
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