File No: BIO/CT/20/000077

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.: 9848887849, Fax: 04023480560, E-Mail: dra@bharatbiotech.com to conduct clinical trial of the new drug or investigational new drug, Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) as per **protocol no.:BBIL/BBV152-A/2020, Version No: 2.0, Date: 26-06-2020** in the below mentioned clinical trial sites.

CT No.: CT- 14/2020

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
Date: 29.06.2020

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(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:	Whole Virion Inactivated Corona Virus Vaccine, [BBV152]			
Therapeutic class:	Vaccine			
Dosage form:	Liquid (Injection for Intramuscular route)			
Composition:	Each dose of 0.5 ml contains			
	Active ingredient	**Quantity**		
	Whole Virion, Inactivated Corona Virus antigen (Strain: NIV-2020-770)	3 mcg	6 mcg	6 mcg
	Inactive ingredients			
	Aluminium Hydroxide gel equivalent to Al+++	250 mcg	250 mcg	250 mcg
	TLR6 Agonist	15 mcg	15 mcg	---
	2-Phenoxyethanol (2PE) I.P.	2.5 mg	2.5 mg	2.5 mg
	Phosphate Buffered Saline	Qs to 0.5 ml	Qs to 0.5 ml	Qs to 0.5 ml
Indications:	For active immunization against Corona Virus infection (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	Dr.. Pandit B D Sharma PGIMS, Rohtak, Haryana.	Institutional Ethics committee, PGIMS, Rohtak, Haryana. ECR/293/Inst/HR/2013/RR-19	Dr. Savita Verma,
2	All India Institute of Medical Sciences AIIMS, Ansari Nagar, 110029 New Delhi	Ethics Committee AIIMS, Ansari Nagar, 110029 New Delhi. ECR/547/INST/DL/2014/RR-17	Dr. Sanjay Kumar Rai
3	King George Hospital, Visakhapatnam, Andhra Pradesh. 530002.	Institutional Ethics committee, King George Hospital, Visakhapatnam, AP. ECR/261/KGH/Inst/AP/2013/RR-20	Dr. Vasu Dev
4	Jeevan Rekha Hospital, Dr. B R Ambedkar Road Belgaum, Karnataka.	Institutional Ethics committee, Jeevan Rekha Hospital, Belgaum, Karnataka. ECR/1242/INST/KA/2019	Dr. Amit Bhate
5	Gillurkar Multispeciality Hospital,20, Reshimbag, Umred Road Nagpur, Maharashtra. 440009	Gillurkar Hospital Ethics committee, Nagpur, Maharashtra. 440009 ECR/1374/INST/MH/2020	Dr. Chandrashekar Gillurkar
6	All India Institute of Medical Sciences, Patna. 801507.	Institutional Ethics committee, All India Institute of Medical Sciences, Patna 801507. ECR/1387/INST/BR/2020	Dr. C. M Singh,

7	Rana Hospital and Trauma center, Rail Vihar Medical college road, Chargawa Gorakhpur, UP. 273001	Institutional Ethics committee, Rana Hospital and Trauma center, Rail Vihar Medical college road, Chargawa Gorakhpur, UP. 273001 ECR/1332/INST/UP/2020	Dr. Ajeet Pratap Singh
8	Institute of Medical sciences & SUM Hospital, K 8, Kalinga Nagar, Ghatikia,Bhubaneshwar - 751003, Odisha	Institutional Ethics committee, IMS, SUM Hospital, K 8, Kalinga Nagar, Ghatikia,Bhubaneshwar - 751003, Odisha.	Dr. Venkat Rao
9	Redkar Hospital, Oxelbag, Dhargal GOA 403513	Institutional Ethics committee, Redkar Hospital, Oxelbag, Dhargal GOA403513 ECR/902/INST/GA/2018	Dr. Sagar Vivek Redkar
10	Prakhar Hospital, 8/219 Arya Nagar, Kanpur UP 208002	Ethics committee, Prakhar Hospital, 8/219 Arya Nagar, Kanpur UP 208002 ECR/1017/INST/UP/2017	Dr. Jitendra Kushwaha
11	SRM Hospital & Research center, SRM Nagar, Potheri, Kattaankulathur Tamil Nadu 603203	Institutional Ethics committee, SRM Hospital & Research center, SRM Nagar, Potheri, Kattaankulathur Tamil Nadu 603203 ECR/431/INST/TL/2013/RR-19	Dr. Satyajit Mohapatra
12	Nizams Institute Medical Sciences & Hospital,Punjagutta Hyderabad, Telangana	Institutional Ethics committee, Nizams Institute Medical Sciences& Hospital, Punjagutta Hyderabad, Telangana ECR/303/INST/AP/2013/RR-19	Dr. Prabhakar Reddy
13	KR Hospital Mysuru Medical Collage, Karnataka	Ethics committee, KR Hospital Mysuru Medical Collage,KarnatakaEC/RENEW/INST/KA/2013/RR-19	Dr. Madhu Kumar R

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

I. Firm is required to conduct Phase I/II clinical trial as per protocol titled "Multicenter Study to Evaluate the Safety, Reactogenicity, Tolerability and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Volunteers" vide Protocol No: BBIL/BBV152-A/2020 Version No: 2.0 Date: 26-06-2020 after approval of Ethics committee.

II. Clinical trial participating sites should have facilities to handle emergency situations such as anaphylaxis

III. The principal investigators should have appropriate qualification & experiences suitable for the conduct of study.

IV. Firm is required to submit results of Phase I clinical trial to the DCGI before initiating the Phase-II study.

V. Firm is required to submit following information/documents & initiate the trial on satisfactory results:

   a. Additional animal toxicity data on other species as and when the studies are completed.

   b. Certificate of analysis of Drug product including adventitious agents and Hemadsorption results along with specification and results of TLR7 in drug product shall be submitted before initiation of clinical trial.

c. Further stability data for batches used for animal toxicity & ongoing stability data of CT batches (accelerated & real time) shall be submitted regularly.
d. Copy of receipt of strain from NIV, Pune and MoU with NIV, if any.
e. 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.

VI. The batches for use in the clinical trial shall be parallely tested at CDL, Kasauli.

Place: New Delhi
Date: 29.06.2020

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