File No: BIO/CT/21/000096

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-BBV152/154-2021** in the below mentioned clinical trial sites.

CT No.: CT- 26/2021

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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Place: New Delhi
Date: 11.08.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
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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] (COVAXIN)		Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154)	
Therapeutic class:	Vaccine		Vaccine	
Dosage form:	Liquid for intramuscular injection		Liquid for intranasal route of administration (nasal drop)	
Composition:	Each dose of 0.5 ml contains		Each single dose (0.5 ml) contains	
	Ingredients	**Quantity**	**Ingredients**	**Quantity**
	Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770	6 mcg	Chimpanzee adenovirus 36 encoding SARS-CoV-2 pre-fusion stabilized spike protein (ChAd36-SARS-CoV-S)	NLT $5x10^{10}$ virus particles per mL
	Aluminium Hydroxide gel eq. to Al+++	250 mcg	Tris-HCl (pH 7.4)	20mM
	TLR 7/8 Agonist	15 mcg	Sodium Chloride	25mM
	2-Phenoxyethanol (2PE)	2.5 mg	Magnesium Chloride	2mM
	Phosphate Buffered Saline	Qs to 0.5 ml	Glycerol	2.5%
			Polysorbate-80	0.1%
Indications:	For active immunization against Corona Virus Infections (COVID-19) caused by SARS-CoV-2.			

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Gleneagles Global Hospitals, Lakdikapul, Hyderabad - 500004	Institutional Ethics Committee, Gleneagles Global Hospitals Lakdikapul, Hyderabad ECR/158/Inst/AP/2013/RR-19	Dr Tapaswi Krishna Patibandla
2	Guru Nanak Hospital, Shiv Colony, National Highway 2Main Delhi Mathura Road Opposite Palwal Bus Stand Palwal -121102	INCLEN Independent Ethics Committee, The INCLEN Trust International, F-1/5, IInd floor okhla industrial area Phase 1, New Delhi–110020 India ECR/109/Inst/DL/2014/RR-20	Dr Abhishek Agarwal
3	JSS Medical College JSS Hospital Agrahara Mysore -570004	Institutional Ethics Committee, JSS Medical College and Hospital 3rd Floor JSS Medical College, Mysore ECR/387/Inst/KA/2013/RR-19	Dr. Prathiba Pereira
4	Sri Guru Ram Rai Institute of Medical and Health Sciences, Patel Nagar,	Institutional Ethics Committee Sri Guru Ram Rai Institute of Medical and Health Sciences,	Dr Sanjeev Kumar

	Dehradun, Uttarakhand-248001	Patel Nagar ECR/710/Inst/UK/2015/RR-19	
	IMS and SUM Hospital, K-8, Kalinga Nagar, Ghatikia Bhubneshwar–751003 Odisha	Institutional Ethics Committee IMS and SUM HospitalK-8, Kalinga Nagar, Ghatikia Bhubneshwar–751003 Odisha ECR/627/Inst/OR/2014/RR-20	Dr E Venkata Rao
	All India Institute of Medical Sciences, Ansari NagarNew Delhi -110029	Institutional Ethics Committee, All India Institute of Medical Sciences Old OT Block Room No 102, AIIMS Hospital, Ansari Nagar, New Delhi -110029	Dr Sanjeev Sinha

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

I. The Phase II clinical trial should be conducted as per protocol No: BBIL-BBV152/154-2021 titled “A Phase 2 randomized, multi-centric, Clinical Trial of Heterologus Prime-Boost Combination of SARS-CoV-2 Vaccines to evaluate the immunogenicity and safety of BBV152 (COVAXIN®) with BBV154 (Adenoviral Intranasal COVID-19 vaccine) in Healthy Volunteers.”
II. Firm is required to submit revised clinical trial protocol for conduct of Phase II clinical trial.
III. Firm is required to submit:
    a. Report for prime-boost immunization with BBV154 vaccine conducted in BALB/c mice.
    b. Copy of the Insurance Certificate
    c. 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
IV. The firm is required to constitute a DSMB to review the safety data of the trial.
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedure and shall have ongoing stability programme.
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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