

File No: BIO/CT/21/000163
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/Booster/2021 Version No: 2.0; Dated 05-01-2022** in the below mentioned clinical trial sites.

CT No.:	CT- 02/2022
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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.
4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

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SOMANI**

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Date: 2022.01.27 22:04:00 +05'30'

Place: New Delhi
Date: 27.01.2022

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

Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Chimpanzee Adenovirus Vected COVID-19 Vaccine (BBV154)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for intranasal route of administration	
Composition:	Each single dose (0.5 ml) contains	
	Ingredients	Quantity
	Chimpanzee adenovirus 36 encoding SARS-CoV-2 pre-fusion stabilized spike protein (ChAd36-SARS-CoV-S)	NLT 5x10 ¹⁰ virus particles per mL
	Tris-HCl (pH 7.4)	20mM
	Sodium Chloride	25mM
	Magnesium Chloride	2mM
	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	All India Institute of Medical Sciences, New Delhi - 110029, India.	Ethics Committee, All India Institute of Medical Sciences, New Delhi -110029, India. ECR/538/Inst/DL/2014/RR-20	Dr Sanjay Rai
2	Jeevan Rekha Hospital, Near Nagshanti motors Showroom, Veer Chambers, Opp Civil Hospital Road, Belagavi-590002	Institutional Ethics Committee, Jeevan Rekha Hospital, Near Nagshanti motors Showroom, Veer Chambers, Opp Civil Hospital Road, Belagavi-590002 ECR/1242/Inst/KA/2019	Dr. Amit Suresh Bhate
3	Prakhar Hospital Pvt Ltd, 8/219, Arya Nagar, Kanpur-208002, Uttar Pradesh, India.	Institutional Ethics Committee, Prakhar Hospital Pvt Ltd, 8/219, Arya Nagar, Kanpur-208002, Uttar Pradesh, India. ECR/1017/Inst/UP/2017/RR-21	Dr Jitendra Singh Kushwaha
4	St. Theresa Hospital, Sanath Nagar, Hyderabad 500018 Telangana	Ethics Committee, St. Theresa Hospital, Sanath Nagar, Hyderabad 500018 Telangana ECR/230/Inst/AP/2013/RR-19	Dr. A. Venkateshwar Rao
5	Gillurkar Multispeciality Hopital, 20, Reshimbag, Umred Road, Nagpur 440009	Gillurkar Hopital, Ethics committee, 20, Reshimbag, Umred Road, Nagpur 440009 ECR/1374/Inst/MH/2020	Dr. Chandrashekhar S Gillurkar

In addition to point 4, the permission is subject to following condition(s):

- I. The Phase III clinical trial should be conducted as per protocol which shall be titled as "Phase 3, Randomized, Multi-Centric, Open-labeled Study to Evaluate Immunogenicity and Safety of BBV154 Booster Dose in Participants Previously Vaccinated with the COVID-19 Vaccines approved under New Drugs & Clinical Trials Rules, 2019" vide Protocol No: BBIL/Booster/2021 Version No: 2.0; Dated 05-01-2022.
- II. Firm is required to submit following:
 - i. Immunogenicity and Safety data of sufficient duration post booster (third) dose & data of Phase III active comparator clinical trial of Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154) permitted by this office vide CT no. CT-01/2022 vide file no. BIO/CT/22/000007.
 - ii. Pharmaceutical development report for Chimpanzee Adenovirus Vectored COVID-19 Vaccine (BBV154).
 - iii. Validation of analytical procedures.
 - iv. Duly signed Insurance certificate issued by Novo Insurance Broking Services Private Limited, Hyderabad for the proposed study.
 - v. 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.
- III. The firm is required to constitute a DSMB to review the safety data.
- IV. The formulation intended to be used in the clinical trial shall be manufactured using validated procedures under GMP conditions and shall have ongoing stability programme.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 27.01.2022

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

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