

File No: BIO/CT/21/000001

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/BBV154/2020 Version No: 2.0; Date: 20-01-2021** in the below mentioned clinical trial sites.

**CT No.: CT- 04/2021**

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.

Place: New Delhi  
Date: 12/02/2021

(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 (0.2 ml) contains	
	<b>Ingredients</b>	<b>Quantity</b>
	Chimpanzee adenovirus 36 encoding SARS-CoV-2 pre-fusion stabilized spike protein (ChAd36-SARS-CoV-S)	NLT $1 \times 10^{10}$ virus particles/SHD
	Tris-HCl (pH 7.4)	20 mM
	Sodium Chloride	25 mM
	Magnesium Chloride	2 mM
	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	Apollo Speciality Hospital, #21, Greams Lane, Chennai,	Institutional Ethics Committee-Clinical Studies, Apollo Speciality Hospital, #21, Greams Lane, Chennai, ECR/37/Inst/TN/2013/RR-19	Dr. C Jagadeesh
2	Felix Hospital, Sector 137, NOIDA, Uttar Pradesh, 201305	Institutional Ethics Committee Felix Hospital, Sector 137, NOIDA, Uttar Pradesh, 201305 ECR/1484/Inst/UP/2020	Dr. Lal Babu Prasad
3	Gillukur Multispeciality Hospital, 20, Reshimbag, Umred Road, Nagpur Maharashtra 440009	Gillukur Hospital Ethics Committee, 20, Reshimbag, Umred Road, Nagpur 440009, Maharashtra ECR/1374/Inst/MH/2020	Dr Vilas T Panchbhai
4	St Theresa Hospital, Sanathnagar, Erragadda, Hyderabad 500018	Ethics Committee, St Theresa Hospital, Sanathnagar, Erragadda, Hyderabad 500018 ECR/230/Inst/AP/2013/RR-19	Dr. A Venkateswara Rao

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 1, Randomized, Double-blinded, Multicenter Study to Evaluate the Reactogenicity, Safety, and Immunogenicity of an Intranasal Adenoviral vector COVID-19 vaccine (BBV154) in Healthy Volunteers" vide Protocol No: BBIL/BBV154/2020 Version No: 2.0; Date: 20-01-2021.
- II. The firm is required to constitute a DSMB to review the safety data.

- III. RCGM approval for conduct of Research and Development, pre-clinical studies & further proceeding to Phase I human clinical trials.
- IV. Firm is required to submit copy of the Insurance Certificate.
- 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.

Place: New Delhi

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