

File No: BIO/CT/22/000007

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-III/2022 Version No: 1.0; Date: 05-01-2022** in the below mentioned clinical trial sites.

CT No.:	CT- 01/2022
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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.

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 Vectored 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	Aatman Hospital, 5, Anveshan Row House, Bopal Gam BRTS, Bopal-Ghuma Road, Bopal, Ahmedabad-380058, Gujarat, India. ECR/1565/Inst/GJ/202	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row House, Bopal Gam BRTS, Bopal-Ghuma Road, Bopal, Ahmedabad-380058, Gujarat, India. ECR/1565/Inst/GJ/202	Dr Chintan B Patel
2	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
3	All India Institute of Medical Sciences, Patna, Bihar	Institutional Ethics Committee, All India Institute of Medical Science Patna Bihar -801507 ECR/1387/Inst/BR/2020	Dr Chandramani Singh
4	Oyster and Pearl Hospitals (Phadnis Clinic Pvt Ltd), 1671-75, Ganeshkhind Road, Shivajinagar, Pune-411005, Maharashtra, India.	Institutional Ethics Committee, Oyster and Pearl Hospitals, Ganeshkhind Road, Shivajinagar, Pune-411005, Maharashtra, ECR/71/Inst/MH/2013/RR-1	Dr Aniket Chandrakant Joshi
5	Pt. BD Sharma Postgraduate Institute of Medical Sciences (PGIMS), UHS, Rothak-124001, Haryana.	Institutional Ethics Committee, Pt. BD Sharma Postgraduate Institute of Medical Sciences (PGIMS), UHS, Rothak-124001, Haryana. ECR/293/Inst/HR/2013/RR-19	Dr Savita Verma

6	Acharya Vinobha Bhawe Rural Hospital, Pediatric Department, Sawangi Meghe, Wardha-442004.	Institutional Ethics Committee, Acharya Vinobha Bhawe Rural Hospital, Pediatric Department, Sawangi Meghe, Wardha-442004. ECR/440/Inst/MH/2013/RR-19	Dr Shilpa Bawankule
7	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
8	Rana Hospital Pvt. Ltd. Rail Vihar Medical College Road Chargawa Gorakhpur 273001	Institutional Ethics Committee, Rana Hospital Pvt. Ltd. Rail Vihar Medical College Road Chargawa Gorakhpur 273001 ECR/1332/Inst/UP/2020	Dr. Ajeet Pratap Singh
9	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

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 titled "A Phase III randomized open label multi-center study to compare immunogenicity and safety of BBV154 with COVAXIN®, and to assess Lot to Lot Consistency of BBV154 in Healthy Volunteers" vide Protocol No: BBIL/BBV154-III/2022 Version No: 1.0; Date: 05-01-2022.
- II. Firm should submit the safety data of sufficient duration post second dose.
- III. Firm is required to submit following:
 - i. Pharmaceutical development report for Chimpanzee Adenovirus Vectedored COVID-19 Vaccine (BBV154).
 - ii. Validation of analytical procedures.
- IV. The firm is required to constitute a DSMB to review the safety data.
- V. 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.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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