

File No: BIO/CT/21/000069

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 Licensing Authority hereby permits M/s. M/s Virchow Biotech Private Limited, Plot No. 4 S.V.Co-op. Industrial Estate Jeedimetla (India) - 500055 Telephone No.: 40-23119481, 64581006 FAX: 40-23119486 E-Mail: NARESH@VIRCHOWBIOTECH.COM conduct clinical trial of the new drug or investigational new drug as per Protocol no.: VB-COVIDVAC/2021-CT1; Version: 1; Version Date: 01.05.2021 in the below mentioned clinical trial sites.

CT No.: CT- 19/2021

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.

Date: 09-Jun-2021
Place: New Delhi

VENUGOPAL
GIRDHARILA
L SOMANI

Digitally signed by VENUGOPAL
GIRDHARILA SOMANI
DN: c=IN, o=MINISTRY OF HOME
AFFAIRS, ou=CDSCO DGHS,
postalCode=431401,
st=Maharashtra,
2.5.4.20=173d03345df62d48963237
9a1471b1da9f0b2bea56c83bfbbe2
154e399b1a77, cn=VENUGOPAL
GIRDHARILA SOMANI
Date: 2021.06.09 16:21:05 +05'30'

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Gam-COVID-Vac combined vector vaccine (Component I & Component II)	
Therapeutic class:	Vaccine	
Dosage form:	Solution (Frozen) for Intramuscular route of administration. When given in two separate doses three weeks apart. Day 0: Component I (0.5 ml) & Day 21: Component II (0.5ml)	
Composition: Component I	Each dose of 0.5 ml contains:	
	Active ingredient	Quantity
	Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene	$1.0 \pm 0.5 \times 10^{11}$ particles
	Inactive ingredients	
	Tris (Hydroxymethyl) amino methane	1.21 mg
	Sodium Chloride	2.19 mg
	Sucrose	25.00 mg
	Magnesium Chloride Hexahydrate	102.00 µg
	EDTA disodium salt dehydrate	19.00 µg
	Polysorbate 80	250.00 µg
	Ethanol 95%	2.50 µg
	Water for injection	Q.s to 0.5 ml
Composition: Component II	Each dose of 0.5 ml contains:	
	Active ingredient	Quantity
	Recombinant adenovirus serotype 5 particles containing the SARS-CoV-2 protein S gene	$1.0 \pm 0.5 \times 10^{11}$ particles
	Inactive ingredients	
	Tris (hydroxymethyl) aminomethane	1.21 mg
	Sodium Chloride	2.19 mg
	Sucrose	25.00 mg
	Magnesium Chloride Hexahydrate	102.00 µg
	EDTA disodium salt dehydrate	19.00 µg
	Polysorbate 80	250.00 µg
	Ethanol 95%	2.50 µg
	Water for injection	Q.s to 0.5 ml
Indication:	For the prevention of the COVID-19 in adults aged over 18.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Government Medical College & Government General Hospital (Old RIMSGGH) Srikakulam-532001, Andhra Pradesh, India.	Institutional Ethics Committee, Government Medical College & Government General Hospital Srikakulam-532001, Andhra Pradesh, India. ECR/492Inst/AP/2013/RR-20	Dr. A. Krishna Veni

2	Medical College and Hospital, No: 88, College Street, Kolkata- 700073, West Bengal- India	Institutional Ethics Committee for Human Research Medical College and Hospital, No: 88, College Street, Kolkata- 700073, West Bengal- India. EC Reg No: ECR/287/Inst/WB/2013/RR-19	Dr. Biplabendu Talukdar
3	ST. ANN'S Hospital, Fatima Nagar, Kazipet, Warangal, Telangana 506004.	St. Ann's Institutional Ethics Committee (SAIEC). Address: St. Ann's Hospital, Kazipet, Warangal Urban, Telangana 506004, India ECR/1297/Inst/TG/201	Dr. Chandrasekhar Valupadas
4	Aman Hospital, 15, Shashwat, Opp. E.S.I Hospital, Sarabhai, Gotri Road, Vadodara, Gujarat- 390021	Institutional Ethics Committee Aman Hospital and Research Center 15, Shashwat, Opp. E.S.I Hospital, Sarabhai, Gotri Road, Vadodara, Gujarat- 390021. EC ECR/857/Inst/GJ/2016/RR-19	Dr. Aman Khanna
5	S R Kalla Memorial Gastro & General Hospital Address: 78-79, Dhuleshwar Garden, Sardar Patel Marg, C-Scheme, JAIPUR – 302001	S R Kalla Memorial Ethics Committee for Human Research Address: 78-79, Dhuleshwar Garden, Sardar Patel Marg, C-Scheme, JAIPUR – 302001, INDIA ECR/8/Inst/Raj/2013/RR-19	Dr. Avinash Agarwal
6	PT. D B Sharma, Post Graduate Institute Medical Sciences, University of Medical Sciences UHS, Rohtak	Institutional Ethics Committee (IEC), Post Graduate Institute Medical Sciences, University of Medical Sciences UHS, Rohtak. ECR/ 293/Inst/HR/2013/RR-19	Dr. Savita Verma

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

- I. The Phase III clinical trial should be conducted as per title "A Randomized, Multi-Center, Phase III Comparative Clinical Trial to Evaluate the Safety and Immunogenicity of Virchow Biotech Manufactured VB-COVIDVAC Combined Vector Vaccine in Healthy Adult Human Subjects" Protocol No: VB-COVIDVAC/2021-CT1; Version: 1; Version Date: 01.05.2021.
- II. The firm is required to submit the following information/documents:
 - a) Change over procedure, Risk assessment, Cleaning validation for manufacturing facilities.
 - b) Validation of analytical procedures carried out by firm.
 - c) stability data or hold time study data for drug substance of component I & II.
 - d) Pharmaceutical development report of formulation developed by M/s Virchow.
 - e) Technology transfer document from RDIF as per WHO TRS requirements.
 - f) Thawed solution stability of drug product (component I & II).
 - g) 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.
 - h) IMP Label as per requirements of rule 66 of ND&CT Rules 2019.
 - i) Copy of the Insurance Certificate.
- III. DSMB is required to be constituted to review the safety data of phase III clinical trial.
- IV. The specifications of Drug substances and Drug product shall be same as that of imported SPUTNIK V vaccine.

- V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOP
AL
GIRDHARIL
AL SOMANI

Digitally signed by VENUGOPAL
GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME
AFFAIRS, ou=CDSCO DGHS,
postalCode=431401,
st=Maharashtra,
2.5.4.20=173d03345df62d4896323
79a1471bfdae9f0b2bea56c83bfbb
e2154e399b1af7, cn=VENUGOPAL
GIRDHARILAL SOMANI
Date: 2021.06.09 16:21:23 +05'30'

Date: 09-Jun-2021
Place: New Delhi

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

