File No: BIO/CT/21/000092

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 Christian Medical College, Ida Scudder Road, Vellore- 632004, Tamil Nadu, Telephone No.: 0416 2283343, Fax: 0416 22833432035, E-Mail:research@cmcvellore.ac.in, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.:Mixing of COVID vaccines study, Version: 1.0 Date: 10th July 2021** in the below mentioned clinical trial sites.

CT No.: CT- 24/2021

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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Date: 2021.08.07 01:11:08 +05'30'

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

Place: New Delhi
Date: 07/08/2021

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)	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD)
Therapeutic class:	Vaccine	Vaccine
Dosage form:	Liquid for intramuscular injection	Liquid for intramuscular injection
Composition:	Each dose of 0.5 ml contains Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770 — 6 mcg Aluminium Hydroxide gel eq. toAl+++ — 250 mcg TLR 7/8 Agonist — 15 mcg 2-Phenoxyethanol (2PE) I.P. — 2.5 mg Phosphate Buffered Saline — Qs to 0.5 ml	Each dose of 0.5 ml contains Replication deficient chimpanzee adeno virus particles encoding SARS-CoV-2 spike (S) glycoprotein — 5×10^{10} virus particles L-Histidine and L-Histidine Hcl. — 10 mM Sodium Chloride — 35 mM Magnesium Chloride — 1 mM Polysorbate 80 — 0.1%(w/v) Sucrose — 7.5%(w/v) Ethanol — 0.5%(w/v) EDTA Disodium Salt — 0.1 mM Water for Injection — q.s. to 0.5 ml
Indications:	Active immunization for prevention of Chikungunya virus infection	

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	M/s Christian Medical College, Ida Scudder Road, Vellore- 632004, Tamil Nadu	Office of research, Institutional review Board, Christian Medical College, Ida Scudder Road, Vellore-632004, Tamil Nadu. ECR/ 326/INST/TN/ 2013)	Dr. Winsley Rose

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

I. The Phase IVclinical trial should be conducted as per protocol titled "Comparison of reactogenicity and immunogenicity of heterologous prime- boost and heterologous boost of ChAdOx1 nCoV-19 (Covishield), BBV152 (COVAXIN) and other COVID vaccines with homologous administration of COVISHIELD and COVAXIN" vide Protocol No: Mixing of COVID vaccines study, Version: 1.0 Date: 10th July 2021.

II. Firm is required to submit the following documents to this office:
   a. Final receipt of Bharatkosh challan for successful payment of fees to Government.
   b. Batch nos. of IMP vaccines to be used in proposed trial.
   c. Valid Ethics Committee registration for the clinical trial site.
   d. Copy of the Insurance Certificate.

III. Firm shall submit Phase IV clinical trial report to CDSCO after completion of the trial.
IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)
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