

Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

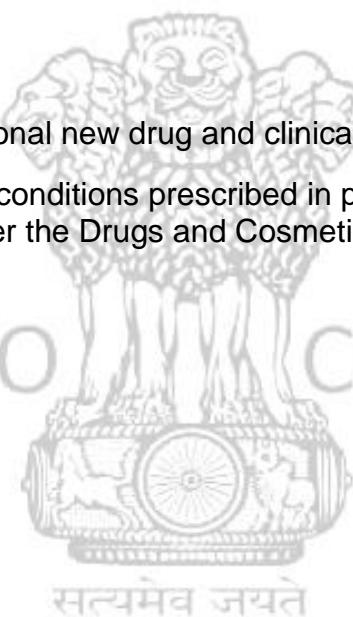
**FORM CT-06**  
(See rules 22, 25, 26, 29 and 30)

**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: 10<sup>th</sup>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.



(Dr. V. G. Soman)  
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  |              | Each dose of 0.5 ml contains  |
|   | Whole Virion, Inactivated Corona Virus antigen Strain: NIV-2020-770 | 6 mcg        | Replication deficient chimpanzee adeno virus particles encoding SARS-CoV-2 spike (S) glycoprotein |
|   | Aluminium Hydroxide gel eq. toAl+++                                 | 250 mcg      | $5 \times 10^{10}$ virus particles  |
|   | TLR 7/8 Agonist   | 15 mcg       | L-Histidine and L-Histidine Hcl.  |
|   | 2-Phenoxyethanol (2PE) I.P.   | 2.5 mg       | 10 mM   |
|   | Phosphate Buffered Saline   | Qs to 0.5 ml | Sodium Chloride   |
|   |   |              | Magnesium Chloride  |
|   |   |              | Polysorbate 80  |
|   |   |              | Sucrose   |
|   |   |              | Ethanol   |
|   |   |              | EDTA Disodium Salt  |
|   |   |              | 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):

- The Phase IV clinical 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: 10<sup>th</sup> July 2021.
- Firm is required to submit the following documents to this office:
  - Final receipt of Bharatkosh challan for successful payment of fees to Government.
  - Batch nos. of IMP vaccines to be used in proposed trial.
  - Valid Ethics Committee registration for the clinical trial site.
  - 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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