

File No: BIO/CT/21/000150

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 Dr. Bikash Medhi of M/s Post Graduate Institute Of Medical Education And Research, Chandigarh, Room Number 4043, Research Block B, PGIMER, Chandigarh-160012 Chandigarh (India) - 160012 Telephone No.: 8728831787 FAX: 0091- 172-2744401 E-Mail: DRBIKASHUS@YAHOO.COM, to conduct clinical trial of the new drug or investigational new drug as per Protocol no.: ICMR/PGIMER-Covishield/Covaxin, Version 3.0 in the below mentioned clinical trial sites.

CT No.:	CT- 13/2022
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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: 24-May-2022

VENUGOPAL G SOMANI
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DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046a34e21727bacb255f6c21c6a4907b04c3d9cb5b58748ee3113c, postalCode=110002, serialNumber=e97f241aa0c0bba41522525ffca0705074b4b97e7c1b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.05.24 15:40:13 +05'30'

Annexure:

Details of New Drug or Investigational New Drug:

COVAXIN vaccine:																							
Name of the new drug or investigational new drug:	Whole Virion Inactivated Corona Virus Vaccine																						
Therapeutic class:	Vaccine																						
Dosage form:	Suspension for injection Route of Administration: Intramuscular																						
Composition:	Each dose of 0.5ml of vaccine contains: <table border="1"> <thead> <tr> <th>Active Ingredients</th><th>Quantity</th></tr> </thead> <tbody> <tr> <td>Whole Virion, Inactivated Corona Virus antigen (Strain: NIV-2020-770)</td><td>6 mcg</td></tr> <tr> <th>Inactive Ingredients</th><th>Quantity</th></tr> <tr> <td>Aluminium Hydroxide gel equivalent to Al⁺⁺⁺</td><td>250 mcg</td></tr> <tr> <td>TLR 7/8 Agonist</td><td>15 mcg</td></tr> <tr> <td>2-Phenoxyethanol (2PE) I.P.</td><td>2.5 mg</td></tr> <tr> <td>Phosphate Buffered Saline</td><td>q.s. to 0.5 mL</td></tr> </tbody> </table> * Produced in Vero cells.	Active Ingredients	Quantity	Whole Virion, Inactivated Corona Virus antigen (Strain: NIV-2020-770)	6 mcg	Inactive Ingredients	Quantity	Aluminium Hydroxide gel equivalent to Al ⁺⁺⁺	250 mcg	TLR 7/8 Agonist	15 mcg	2-Phenoxyethanol (2PE) I.P.	2.5 mg	Phosphate Buffered Saline	q.s. to 0.5 mL								
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2-Phenoxyethanol (2PE) I.P.	2.5 mg																						
Phosphate Buffered Saline	q.s. to 0.5 mL																						
Indications:	For active immunization against Corona Virus Disease (COVID-19) for age ≥18 years when administered in two doses interval of day 0 & day 28.																						
COVISHIELD vaccine:																							
Name of the new drug or investigational new drug:	ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)																						
Therapeutic class:	Vaccine																						
Dosage form:	Solution for injection Route of Administration: Intramuscular																						
Composition:	Each dose of 0.5ml of vaccine contains: <table border="1"> <thead> <tr> <th>Active Ingredients</th><th>Quantity</th></tr> </thead> <tbody> <tr> <td>Replication- deficient chimpanzee adeno virus particles encoding SARS-CoV-2 spike (S) glycoprotein*</td><td>5 x 10¹⁰ virus particles</td></tr> <tr> <th>Inactive Ingredients</th><th>Quantity</th></tr> <tr> <td>L-Histidine and L-Histidine Hydrochloride</td><td>10 mM</td></tr> <tr> <td>Sodium Chloride</td><td>35 mM</td></tr> <tr> <td>Magnesium Chloride</td><td>1 mM</td></tr> <tr> <td>Polysorbate 80</td><td>0.1% (w/v)</td></tr> <tr> <td>Sucrose</td><td>7.5% (w/v)</td></tr> <tr> <td>Ethanol</td><td>0.5% (w/v)</td></tr> <tr> <td>EDTA Disodium Salt</td><td>0.1 mM</td></tr> <tr> <td>Water for Injection</td><td>q.s. to 0.5 ml</td></tr> </tbody> </table> * Produced in genetically human embryonic kidney (HEK) 293 cells.	Active Ingredients	Quantity	Replication- deficient chimpanzee adeno virus particles encoding SARS-CoV-2 spike (S) glycoprotein*	5 x 10 ¹⁰ virus particles	Inactive Ingredients	Quantity	L-Histidine and L-Histidine Hydrochloride	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
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Indications:	For active immunization of individuals of ≥18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.																						

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Post Graduate Institute of Medical Education and Research, Room No. 6006, IEC Office, 6 th Floor P N Chuttani Block, Chandigarh – 160012, India.	Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research, Room No. 6006, IEC Office, 6 th Floor P N Chuttani Block Chandigarh – 160012, India. [ECR/25/Inst/CH/2013/RR-20]	Dr. Madhu Gupta

In addition to point 4, the permission is subject to following condition(s):

- I. The Phase IV clinical trial should be conducted as per protocol titled “Safety, tolerability and immunogenicity after administration of Covid-19 vaccine in homologous prime/boost schedule [Covishield: Covishield; Covaxin: Covaxin] as compared with heterologous prime/boost [Covishield: Covaxin; Covaxin: Covishield] schedule among adults in North India: An observer blind non inferiority randomized Control Trial” [Protocol no.: ICMR/PGIMER-Covishield/Covaxin, Version 3.0]
- II. Firm is required to submit the following documents/information:
 - a. Revised Investigator's Brochure for the proposed clinical trial as per revised protocol based on the recommendations of SEC experts dated 11.04.2022.
 - b. Copy of Ethics committee approval for the proposed study.
 - c. Copy of Insurance certificate for proposed clinical trial.
- III. The firm is required to constitute a DSMB to review the safety data.
- IV. 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
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 24-May-2022

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

Digitally signed by VENUGOPAL G SOMANI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA), pseudonym=112046734e217227bacb255748752c4568249073e33e933d9e5b587483e3113e, postalCode=110002, st=DELHI, serialNumber=970446400ba941522525ffca0705074b4997eb2f4b5c8d81cf282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.05.24 15:40:21 +05'30'