File No: BIO/CT/22/000018

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 Mr. Michael C Vernekar of M/s Serum Institute Of India Pvt. Ltd., S. No. 105-110, Manjari Bk. Manjari Bk. Pune (India) - 412307 Telephone No.: null FAX: null E-Mail: MICHAELVERNEKAR@YAHOO.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: COVOVAX-Booster in the below mentioned clinical trial sites.

CT No.: CT- 05/2022

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 G SOMANI

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Place: New Delhi
Date: 22-Mar-2022

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine [COVOVAX]	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for intramuscular administration	
Composition:	Each dose of 0.5 mL of vaccine contains:	
	Name of ingredients	**Quantity**
	SARS-CoV-2 Rs*	5 µg
	Matrix-M1(Matrix A & Matrix C)	50 µg
	Sodium Phosphate Dibasic Heptahydrate	2.465mg
	Sodium Phosphate Monohydrate Monobasic	12.36 mM
	Sodium Chloride	300 mM
	Polysorbate 80	0.01% w/v
	Water for Injection	q.s. to 05ml
	*produced in *baculovirus*-infected *Spodoptera frugiperda (Sf9)* insect cells	
Indication(s):	For active immunization to prevent COVID-19 caused by SARS CoV-2 in individuals 18 years of age and older when administered in two dose schedule of day 0 & day 21.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Hamdard Institute of Medical Sciences and Research with Centre for health Research and Development (CHRD),Society for Apllied Studies (SAS),Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062, India.	Institute of Ethics Committee, Jamia Hamdard Institutional Ethics Committee, Hamdard Nagar, New Delhi South, Delhi - 110062 India [ECR/48/Inst/DL/2013/RR-19]	Dr. Sunil Kohli
2	JSS Academy of Higher Education and Research, Bannimantap Road, Sri Shivarathreeshwara Nagara, Bannimantap A Layout, Bannimantap, Mysore, Karnataka-570015, India.	Institutional Ethics Committee, 3rd Floor, JSS Medical College, SS Nagar, Mysuru – 570015 [ECR/387/Inst/KA/2013/RR-19]	Dr Praveen Kulkarni
3	Vadu Rural Health Program, KEM Hospital Research Centre, Pune.	Institute of Ethics Committee, KEM Hospital Research Centre Ethics Committee KEM Hospital Research Centre, TDH building, Sardar oodliar Road, Rasta Peth, Pune-411011, Maharashtra [ECR/272/Inst/MH/2013/RR-22]	Dr. Aditi Pusalkar – Apte
4	Bharati Vidyapeeth University Medical College,	Institute of Ethics Committee, Bharati Vidyapeeth University Medical College,	Dr. Sanjay Kewalchand

	Pune	Pune	Lalwani,
5	Dr. D. Y. Patil Medical College Hospital and Research Centre, Department of Medicine, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra-411018, India	Ethics Committee, Dr. D.Y. Patil Vidyapeeth, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra- 411018 [ECR/361/Inst/MH/2013/RR-19]	Dr. Srikanth Tripathy
6	Kalinga Institute of Medical Sciences, Kushabhadra Campus , KIIT Campus, 5, KIIT Road, Patia, Bhubaneswar, Odisha 751024, India	Institutional Ethics Committee-KIMS, Kalinga Institute of Medical Sciences, Khushabhadra Campus 5, KIIT University, Patia Bhubneswar Khorda, Orissa –751024 India [ECR/321/Inst/OR/2013/RR-20]	Dr. Sonali Kar
7	Department of Community Medicine, Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra - 442102, India	Institutional Ethics Committee, (Department of Pharmacology) Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra –442102 [ECR/47/Inst/MH/2013/RR-19]	Dr. Abhishek Raut

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

1. The Phase III clinical trial should be conducted as per protocol titled “A phase 3, observer-blind, randomized, controlled study to evaluate the safety and immunogenicity of a booster dose of COVOVAX in Indian adults who have received primary vaccination against COVID-19”[Protocol no.: COVOVAX-Booster]
2. The firm is required to submit the following information/documents:
   a) Revised clinical trial protocol to include the objective of at least 2 fold rise in the neutralizing antibody titres in the investigational arm comparing with approved homologous booster vaccine in line with recommendations of SEC (Covid) dated 04/03/2022 in addition to the existing objectives along with Informed Consent Form (ICF) or Patient Information Sheet (PIS) and CRF.
3. Only approved formulation of SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine [COVOVAX] shall be used in the said Phase III clinical trial.
4. The firm is required to constitute a DSMB to review the safety data.
5. Firm is required to submit Investigator Brochure & EC approval as per the revised clinical trial protocol.
6. Copy of 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.
7. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
8. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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