

File No: BIO/CT/20/000186
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 Serum Institute of India Pvt. Ltd., S. No. 105-110, Manjari Bk. Pune (India) - 412307 Telephone No.: null, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: ICMR/SII-COVOVAX Version No: 4.0 Date: 25 JAN 2021** in the below mentioned clinical trial sites.

CT No.: CT- 03/2021

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.

Place: New Delhi
Date: 11.02.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
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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	
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	50 µg
	Sodium Phosphate Dibasic Heptahydrate	12.63 mM
	Sodium Phosphate Monohydrate Monobasic	12.36 mM
	Sodium Chloride	300 mM
Indication(s):	Polysorbate 80	0.01% w/v
	Prevention of COVID 19 infection	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Sahyadri Super Speciality Hospital, Survey no.185A, Shastri Nagar, Yerwada, Nagar road, Pune, Maharashtra- 411004, India	Sahyadri Hospitals Ltd. Ethics committee, Sahyadri Clinical Research & Development Center (A Unit of Sahyadri Hospitals Ltd.), 33/34B, Makarand Bhawe Path, Karve Road, Pune-411004, Maharashtra, India ECR/493/Inst/MH/2013/RR-19	Dr. Govind Kulkarni
2	KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi Karnataka 590010, India	Institutional Ethics Committee, KLE University, KLE Dr.PK Hospital and MRC, Nehru Nagar Belagavi Belagavi (Belgaum), Karnataka - 590010 India ECR/211/Inst/KA/2013/RR-19	Dr. Madhav Prabhu
3	Jawaharlal Institute of Postgraduate Medical Education and Research, Dhanvantri Nagar, Puducherry-605006, India	IEC Intervention Studies, JIPMER JIPMER Dhanvantari Nagar, Puducherry -605006, India, ECR/342/Inst/PY/2013/RR-19	Dr. Tamarasu Kadiravan
4	Department of Community Medicine, Christian Medical College & Hospital, Brown Rd, Ludhiana, Punjab 141008, India	Institutional Ethics Committee, Christian Medical College & Hospital, 2 nd Floor, Nr. Ward 15, Room no: 3201, Christian Medical College & Hospital, Brown road, Ludhiana-141008, Punjab, India ECR/120/Inst/PB/2013/RR-19	Dr. Clarence Samuel
5	Hamdard Institute of Medical Sciences and Research with Centre for	Jamia Hamdard Institutional Ethics Committee, Hamdard Nagar, New Delhi South, Delhi Delhi -110062	Dr. Sunil Kohli

	health Research and Development (CHRD), Society for Applied Studies (SAS),Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062, India	India ECR/48/Inst/DL/2013/RR-19	
6	KIMS Hospital and Research centre, Krishna Rajendra Rd, Vishweshwarapura, Bengaluru, Karnataka 560004	KIMS Institutional Ethics Committee Kempegowda Institute Of Medical Sciences Attimabbe Road Banashankari 2nd Stage Bangalore 560070 ECR/216/Inst/Kar/2013/RR-19	Dr. Ashwath Narayana
7	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 411018 ECR/361/Inst/MH/2013/RR-19	Dr. Varsha Bhatt
8	Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha, Maharashtra-442004,India	Institutional Ethics Committee of DMIMS, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe) Wardha Maharashtra - 442004 India ECR/440/Inst/MH/2013/RR-19	Dr. Abhay Gaidhane
9	Institution of Medical Science and SUM Hospital, K8,Lane 1, Kalinganagar, Bhubaneswar, Khordha, Orissa –751003,India	Institutional Ethics Committee, IMS & SUM Hospital Bhubaneswar, K-8 Kalinga Nagar, Shampur, Bhubaneswar, Khordha Orissa – 751003 ECR/627/Inst/OR/2014/RR-20	Dr. Rakhi Ludam
10	Amrita Institute of Medical Sciences, Department of General Medicine, Ponekkara, Kochi, Kerala-682041, India	Institutional Ethics Committee Amrita Institute of Medical Sciences AIMS-Ponekkara Kochi Edappally Ernakulam Kerala-682041 India ECR/129/Inst/KL/2013/RR-19	Dr. Dipu Thareparambil S
11	School of Tropical Medicine108, Chittaranjan Ave, Calcutta Medical College, College Square, Kolkata, West Bengal 700073, India	Clinical Research Ethics Committee, C/o. Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, 108 Chittaranjan Avenue, Kolkata –700073 ECR/194/Inst/WB/2013/RR-20	Dr. Santanu Tripathy
12	Noble Hospital, 153, Road, Magarpatta, Hadapsar, Pune, Maharashtra-411013, India	Noble Hospital Institutional Ethics Committee, Noble Hospitals Pvt. Ltd. ,Room No 5, Clinical, Research Department Noble Annex, 153 A, Magarpatta City Road, Hadapsar 411013, India ECR/259/Inst/MH/2013/RR-19	Dr. Sidram Raut

13	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
14	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
15	JSS Academy of Higher Education and Research, Bannimantap Road, Sri Shivarathreeswara Nagara, Bannimantap A Layout, Bannimantap, Mysore, Karnataka-570015, India	Institutional Ethics Committee, 3 rd Floor, JSS Medical College, SS Nagar, Mysuru –570015 ECR/387/Inst/KA/2013/RR-19	Dr. Praveen Kulkarni
16	KEM Hospital Research Centre, Vadu Rural Health Program, Vadu Budruk, Taluka Shirur, Pune, Maharashtra-412216, India	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth, Pune-411011, Maharashtra, India. ECR/272/Inst/MH/2013/RR-19	Dr. Ashish Bavdekar
17	Super Speciality Hospital, Government Medical College and Hospital, Tukdoji Square, Nagpur, Maharashtra-440009, India	Institutional Ethics Committee, GMC Nagpur, Government Medical College and Hospital, Medical Square, Hanuman Nagar, Nagpur, Maharashtra –440003, India ECR/43/Inst/MH/2013/RR-19	Dr. Sushant Meshram
18	Department of Pulmonary, Critical Care and Sleep Medicine, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029, India	Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), Room No. 102, 1st Floor, Old OT Block, Ansari Nagar, New Delhi –110029 India ECR/538/Inst/DL/2014/RR-20	Dr. Vijay Hadda
19	All India Institute of Medical Sciences, Department of Pharmacology, Gorakhpur, Uttar Pradesh 273008, India	Institutional Human Ethics Committee, All India Institute Of Medical Sciences, Gorakhpur, Opp Army Public School Kunraghat, Gorakhpur Uttar Pradesh -273008 India ECR/1476/Inst/UP/2020	Dr. Hira Lal Bhalla

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

1. The Phase II/III clinical trial should be conducted as per protocol titled "A phase 2/3, observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant] in Indian adults"
2. Firm is required to submit revised clinical trial protocol with double blind study design and as per recommendations of Subject Expert Committee (SEC) meeting dated 03.02.2021 that the participants randomized to the placebo arm may be unblinded 60 days after the second dose upon request of the clinical trial participant only. Such participant may be offered investigational vaccine as per the dose and schedule prescribed in the protocol.
3. Firm is required to submit copy of contract entered by the ICMR with the investigator/institutions.
4. The firm is required to constitute a DSMB to review the safety data.
5. Firm is required to submit Principal Investigators undertaking & Ethics committee approvals for revised clinical trial protocol.
6. 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.
7. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 11.02.2021

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