

File No: BIO/CT/21/000059
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 Premium Serums And Vaccines Pvt. Ltd., 406, B Wing, Highway Rose Co-op. Housing Society 92, Dixit Road Extn., Vile Parle (East), Mumbai (India) - 400057 Telephone No.: 022-26119940 FAX: 022-26119940 E-Mail : premiumserums@gmail.com to conduct clinical trial of the new drug or investigational new drug as per protocol number: SII-COVID19-EqS/IN-01, version no. 3 dated 17.05.2021 in the below mentioned clinical trial sites.

CT No.: CT- 18/2021

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: 09-JUN-2021

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

Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Anti-COVID19 Serum [Equine Anti Covid Antibody Fragments F(ab') ₂]	
Therapeutic class:	Antisera	
Dosage form:	Intravenous infusion	
Composition:	Each 1 ml of Anti-COVID19 serum contains:	
	Name of ingredients	Quantity
	COVID-19 Antiserum Immunoglobulin fragment F(ab') ₂	NLT 100000 PRNT50
	Glycine IP/BP	1.88 %
	Sodium Chloride	0.9 %
	Water for Injection	q.s.
Indication(s):	For the treatment of SARS-CoV-2 infection/COVID19 disease.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Prakash Institute of Medical Sciences & Research, Urun-Islampur, Islampur-Sangli Road, Islampur, Tal-Walwa, Dist. Sangali-415409, Maharashtra,.	Prakash Medical College Institutional Ethics Committee, Prakash Institute of Medical Sciences & Research, Urun-Islampur, Islampur- Sangli Road, Dist. Sangali-415409 Maharashtra, India EC No.: ECR/1052/Inst/MH/2018	Dr. Vijay Kumar Patil
2	Rajarshree Chhatrapati Shahu Maharaj Government Medical College & Chhatrapati Pramila Raje General Hospital, Dasara Chauk, Town Hall, Bhausingji Road, Kolhapur-416012.	Rajarshree Chhatrapati Shahu Maharaj Government Medical College & Chhatrapati Pramila Raje Hospital Kolhapur Institutional Ethics Committee 2 (RCSMGMCI EC2), Dasara Chauk, Town Hall, Bhausingji Road, Kolhapur- 416012, Maharashtra. EC No.: ECR/703/Inst/MH/2015/RR-20.	Dr. Vijay Kumar Barge

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

1. The Phase I clinical trial should be conducted as per protocol titled " A Phase I, Randomized, Controlled, Open Label Study to Assess the Safety and Efficacy of COVID-19 Antiserum in Adult Patients with SARS-CoV-2/COVID-19 Disease" vide protocol no. SII-COVID19-EqS/IN-01, version no. 3 dated 17.05.2021"
2. Firm is required to submit repeated dose toxicity study report in rabbits before start of Phase I trial of Anti-COVID19 Serum.
3. The firm is required to constitute a DSMB to review the safety data.
4. 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.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
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