

File No: BIO/CT/20/000178

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. Parag Surendra Shah of M/s Bharat Serums And Vaccines Limited, 17th Floor, Hoechst House, Nariman Point Mumbai (India) – 400 021, Telephone No. 022-66560900, FAX: 022-665660901, E-mail: Parag.shah@bharatserums.com to conduct to conduct clinical trial of the new drug or investigational new drug as per protocol number: BSV_EQ-AB_20_08, Version 02 dated 30.12.2020 in the below mentioned clinical trial sites.

CT No.: CT- 01/2021

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.

Date: 19-JAN-2021
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Equine COVID 19 Antiserum (Liquid Injection)	
Therapeutic class:	Anti sera (Equine)	
Dosage form:	Solution for Infusion (IV route of administration)	
Presentation:	5 ml vial	
Composition:	Each 1 ml contains:	
	Name of Active ingredient	Quantity
	Equine COVID19 Antiserum (source of COVID-19 antigen: M/s BSV Bioscience, Inc., United States)	25 mg (NLT 1:10000)
	Name of Inactive ingredients	Quantity
	Sodium Chloride	9 mg
	Glycine	3 to 4.5 mg
	Water for injection	q.s. to 1.0 ml
Indications:	For use in treatment of COVID-19 infected patient.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Jehangir Hospital, 32, Sassoon Road, Pune - 411 001 (For phase I & II clinical trial)	Ethics Committee, Jehangir, Clinical Development Centre Pvt. Ltd. Jehangir Hospital, 32, Sassoon Road, Pune - 411 001. ECR/352/INST/MH/2013/RR-19	Dr. Piyush Chaudhari
2	Hindusthan Hospital, 522/3, Udayampalayam Road, Peelamedu, Coimbatore, Tamil Nadu - 641 028 (For phase II clinical trial)	Institutional Human Ethics Committee, Hindusthan Hospital, 522/3, 523/3, Nava India Road, Udayampalayam, Coimbatore, Tamil Nadu-641 028, India ECR/1376/Inst/TN/2020	Dr. Srikanth Krishnamurthy

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

- I. The clinical trial should be conducted as per approved protocol titled "A Prospective, Randomized, Multi-center, Open label, Phase 1/2 study to Evaluate the Safety and Efficacy of Equine COVID-19 Antiserum [F(ab')₂] (BSVEQAb) plus Standard of Care in Comparison to Standard of Care alone in COVID-19 RT-PCR positive Patients" vide Protocol no. BSV_EQ-AB_20_08, Version 02 dated 30.12.2020.
- II. The results of Phase I clinical trial should be submitted for review by Subject Expert Committee (SEC) before initiation of Phase II clinical trial.
- III. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- IV. DSMB should be constituted to evaluate the safety data.
- V. Firm is required to submit the following information/documents:
 - a) Application in Form CT-10 for manufacturing of Equine COVID-19 Antiserum at Ambarnath facility for clinical trial purpose as per the requirements of NDCT Rules, 2019.
 - b) Copy of Form 29 license for manufacturing of Equine COVID-19 Antiserum at Ambarnath facility for clinical trial purpose as per the requirements of Drugs and Cosmetics Rules, 1945.

- c) Certificate of Analysis of drug substance drug product (at least 3 batches) manufactured in Ambernath (cGMP facility) including sterility testing.
- d) Real time/temp. and accelerated stability data (at least 3 batches) of drug product manufactured in Ambernath facility and ensure the stability of product at the time of use in proposed Phase I/II clinical trial of Equine COVID 19 Antiserum (Liquid Injection).
- e) Details of other clinical trial sites along with undertaking, CVs, Medical registration certificate and GCP training of principal investigators prior to initiation of Phase II clinical trial.

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