File No: BIO/CT/20/000150

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 M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:varma.bhupathiraju@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. BECT063/Equine.CoV.Ab-Phase-I/CTP-01, Version No. 1.1 dated 07.10.2020** in the below mentioned clinical trial sites.

CT No.: CT- 21/2020

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 GIRDHARILAL SOMANI

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Date: 2020.10.16 18:15:20 +05'30'

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

Date : 16.10.2020
Place: New Delhi

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
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-2Equine Antiserum Immunoglobulin (Purified F(ab')$_2$ fragment)	
Therapeutic class:	Anti sera (Equine)	
Dosage form:	Solution for Injection	
Composition:	Each 1 ml contains	
	Name of Active ingredient	**Quantity**
	SARS-CoV-2 virus neutralization titer	NLT 10000 / mL as measured by PRNT $_{90}$ assay
	Name of Inactive ingredients	**Quantity**
	Glycine	22.5mg
	Sodium Chloride	0.7mg
	Water for injection	q.s to 1.0 ml
Indications:	To treat patientswith Covid-19disease	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	All India Institute of Medical Sciences, Patna, Phulwarisharif, Bihar -801507 India	Institutional Ethics Committee, All India Institute of Medical Sciences, Patna, Phulwarisharif, Bihar - 801507 India ECR/1387/Inst/BR/2020	Dr. Chandramani Singh
2	Visakha Institute of Medical Sciences (VIMS),S.NO 97/2, Hanumanthawaka, Chinagadilli Village, Visakhapatnam (India) - 530040	Ethics committee Visakha Institute of Medical Sciences (VIMS),S.NO 97/2, Hanumanthawaka,Chinagadilli Village, Visakhapatnam (India) - 530040 ECR/1421/Inst/AP/2020	Dr. P. Venugopal

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 phase I, open label, parallel, randomised trial to assess the safety and efficacy of SARS-CoV-2 Equine Antiserum Immunoglobulin (Purified F(ab')$_2$fragment) in hospitalised COVID-19 patients with moderate disease in addition to standard of care." vide Protocol no. BECT063/Equine.CoV.Ab-Phase-I/CTP-01, Version No. 1.1 dated 07.10.2020.

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