

File No: BIO/CT/20/000039
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 Cadila Pharmaceuticals Limited, 1389, Dholka, Ahmedabad-382225 Gujarat, India Telephone No.: 2714-221481 FAX: 2714-220315 E-Mail: sani.prajapati@cadilapharma.co.in to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: CRSC20004 Version-02, dated 10th April 2020** in the below mentioned clinical trial sites.

CT No.: CT- 07/2020

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.

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:	<i>Mycobacterium w</i> (Heat Killed)	
Therapeutic class:	Immunomodulator	
Dosage form:	Suspension for injection	
Composition:	Each 0.1 ml contains:	
	Name of ingredients	Quantity
	<i>Mycobacterium w</i> (Heat Killed)	0.5 x 10 ⁹ Cells
	Name of Inactive ingredients	Quantity
	Sodium Chloride, I.P.	0.9% w/v
	Thiomersal I.P.	0.01% w/v
	Water for injection, I.P.	q.s.
Indications:	To be used for Improvement in organ dysfunction and reducing overall mortality associated with COVID-19 in critically ill patients	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Post Graduate Institute of Medical Education and Research, Sector 12, Chandigarh 160012 (India).	Ethics committee, Post Graduate Institute of Medical Education and Research, Sector 12, Chandigarh 160012 (India). ECR/25/Inst/CH/2013/RR-1	Dr. Inderpaul Singh Sehgal
2	All India Institute of Medical Science & Associated Hospitals AIIMS Campus, Saket Nagar, Bhopal, Madhya Pradesh 462020	Institutional Ethics Committee of All India Institute of Medical Sciences, Bhopal, Madhya Pradesh 462020	Dr. Sarman Singh
3	All India Institute of Medical Science A Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	Ethics committee, All India Institute of Medical Science A Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	Dr. Anant Mohan

The clinical trial should be conducted as per protocol titled "A clinical trial to evaluate the safety and efficacy of Mw in critically ill patients suffering from COVID 19 infection" vide protocol number: CRSC20004 version-02, dated 10th April 2020.

Firm is required to submit details of the 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.

Place: New Delhi

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