

File No: BIO/CT/20/000042  
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](mailto:sani.prajapati@cadilapharma.co.in) to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: CRSC20006 Version-02, dated 15<sup>th</sup> April 2020** in the below mentioned clinical trial sites.

**CT No.: CT- 09/2020**

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:	
	<b>Name of ingredients</b>	<b>Quantity</b>
	<i>Mycobacterium w</i> (Heat Killed)	0.5 x 10 <sup>9</sup> Cells
	<b>Name of Inactive ingredients</b>	<b>Quantity</b>
	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 in adult COVID 19 positive patients hospitalized but not critically ill.	

**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 phase III clinical trial should be conducted as per protocol titled "A Randomized, Double-blind, Two arm, controlled clinical trial to compare the Efficacy and Safety of *Mycobacterium w* (Mw) administered along with standard of care versus Placebo administered along with standard of care, in adult, COVID 19 positive patients hospitalized but not critically ill" vide Protocol Number: CRSC20006 Version-02, dated 15<sup>th</sup> 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