

File No: BIO/CT/20/000154
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-04, dated 07th October 2020** in the below mentioned clinical trial sites.

CT No.: CT- 24/2020

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
Date: 27.10.2020

(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).	Institutional 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	Sundar Lal Hospital, Institute of Medical Sciences, Banaras Hindu University, Department of Anaesthesiology & Critical Care Institute of Medical Sciences, B.H.U., Varanasi-221005	Institutional Ethics Committee Institute of Medical Sciences Banaras Hindu University Varanasi-221005, Uttar Pradesh, India	Dr Bikram Gupta
3	All India Institute of Medical Science, A Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	Institutional Ethics committee, All India Institute of Medical Science, A Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029	Dr Randeep Guleria
4	All India Institute of Medical Science, Great Eastern Rd, AIIMS Campus, Tatibandh, Raipur, Chhattisgarh 492099	Institutional Ethics Committee, All India Institute of Medical Science, Great Eastern Rd, AIIMS Campus, Tatibandh, Raipur, Chhattisgarh 492099 ECR/ 714/ Inst/CT/2015-RR-18	Dr. Md. Sabah Siddiqui
5	All India Institute of Medical Sciences, Saket Nagar, Bhopal Madhya Pradesh, India	Institutional Ethics Committee, All India Institute of Medical Sciences, Saket Nagar, Bhopal Madhya Pradesh, India	Dr Sarman Singh

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6	Grant Government Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai-400008	Institutional Ethics Committee, Grant Government Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai-400008 ECR/382/Inst/MH/2013/RR-19	Dr. Akash Khobragade
7	Apollo hospital, Madurai, Tamilnadu –625002	Institutional Ethics Committee, Apollo hospital, Madurai, Tamilnadu –625002 ECR/43/Inst/TN/2013/RR-19	Dr. Hari Krishnan
8	All India Institute of Medical Sciences, Phulwari-sharif, Patna –810507	Institutional Ethics Committee, All India Institute of Medical Sciences, Phulwari-sharif, Patna –810507	Dr. Deependra Kumar Rai

The phase III 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-04, dated 07.10.2020.

Firm is required to submit Ethics Committee approvals.

Place: New Delhi
Dated 27.10.2020

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