File No: BIO/CT/20/000041

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.: CRSC20005 Version-02, dated 15th April 2020** in the below mentioned clinical trial sites.

CT No.: CT- 08/2020

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: 2020.04.22 10:48:37 +05'30'

Place: New Delhi

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

File No: BIO/CT/20/000041

Annexure:

Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td colspan="2">Mycobacterium w (Heat Killed)</td></tr>
<tr><td>Therapeutic class:</td><td colspan="2">Immunomodulator</td></tr>
<tr><td>Dosage form:</td><td colspan="2">Suspension for injection</td></tr>
<tr><td rowspan="8">Composition:</td><td colspan="2">Each 0.1 ml contains:</td></tr>
<tr><td>Name of ingredients Quantity</td><td>Quantity</td></tr>
<tr><td>Mycobacterium w (Heat Killed)</td><td>0.5 x 10^9 Cells</td></tr>
<tr><td>Name of Inactive ingredients</td><td>Quantity</td></tr>
<tr><td>Sodium Chloride, I.P.</td><td>0.9% w/v</td></tr>
<tr><td>Thiomersal I.P.</td><td>0.01% w/v</td></tr>
<tr><td>Water for injection, I.P.</td><td>q.s.</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Indications:</td><td colspan="2">Preventing COVID 19 in subject at risk of getting infected with COVID-19.</td></tr>
</table>

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, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of *Mycobacterium w* in preventing COVID-19 in subjects at risk of getting infected with COVID-19" vide Protocol Number: CRSC20005 Version-02, dated 15th April 2020 with the condition that serology shall be conducted initially and at the end of one of the study period.

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.

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2020.04.22 10:48:47 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
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Place: New Delhi