

File No: BIO/CT/19/000032
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 Mr. Sanjay Maheshwari of M/s Cadila Healthcare Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213 Telephone No.: 7926868100 FAX: 7926862362 EMail: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no. RUTIP2-2019-01, version 2.0** in the below mentioned clinical trial sites. **dated 4 November, 2019.**

CT No.: CT- 01/2020

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: 20-JAN-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:	Inactivated Therapeutic Tuberculosis Vaccine. (RUTI [®] Vaccine)		
Therapeutic class:	Vaccine		
Dosage form:	Powder (Lyophilized)		
Composition:		1 vial of lyophilized powder contains: (µg)	1 vial of reconstituted suspension contains: (reconstitution in 0.4 mL water for injection) (µg/ml)
	FCMtb	33.30	83.30
	Sucrose	20,000.00	50,000.00
	Soy lecithin ¹	422.90	1,057.30
	Sodium cholate	46.00	115.00
	Sodium chloride ²	10.40	26.00
	Ethanol ³	q.s.	--
	Water for Injection	q.s	--
	¹ Containing Phosphatidylcholine (Not less than [NLT] 94.0%) ² Added as NaCl 0.34% solution prepared from a 0.9% NaCl solution ³ It disappears in the course of processing		
Indications:	Treatment of Drug susceptible Tuberculosis and Multidrug Resistant Tuberculosis		

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, Ansari Nagar, New Delhi - 110 029.	Institutional Ethics committee, Room No 102, First floor, Old O.T. Block, AIIMS, Ansari Nagar, New Delhi 110029, ECR/547/Inst/DL/2014/RR-17)	Dr. Randeep Guleria
2	Department of Microbiology, Agartala Govt. Medical College, Tripura.	Institutional Ethics Committee at Agartala Government Medical College and G.B Pant Hospital Agartala Tripura-799006 India (ECR/937/Inst/TR/2017)	Dr. Tapan Majumdar

In addition to point 3, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled "Double-Blind, Randomized, Placebo-Controlled Phase IIb Clinical Trial to Investigate the Efficacy of RUTI[®] Therapeutic Vaccination as adjuvant of Tuberculosis chemotherapy" Protocol no. RUTIP2-2019-01, version 2.0, dated 4 November, 2019.
- II. Firm should constitute DSMB to monitor the safety every 3 weeks before initiation of the Clinical Trial.
- III. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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