

File No: BIO/CT/22/000088
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 Ms. Mona Gogia of M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road Dholka Dholka (India) – 387810 Telephone No.: 2714-221481 FAX: 2714-220315 E-Mail : mona.gogia@cadilapharma.co.in, to conduct clinical trial of the new drug or investigational new drug as per Protocol No. CRSC22001, Version 04, Dated - 20/12/2022 in the below mentioned clinical trial sites.

CT No.: CT-02 /2023

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: 03-FEB-2023

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

Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Recombinant Rabies G Protein Vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for Intramuscular injection	
Composition:	Each dose of 0.5 ml vaccine contains:	
	Ingredients	Quantity
	rRabies G Protein	50.00 µg
	Disodium Hydrogen Phosphate Anhydrous IP	0.87 mg
	Monobasic Sodium Phosphate Monohydrate BP	0.88 mg
	Sodium Chloride	8.76 mg
	Tergitol NP	0.1 µL
	Sodium Hydroxide	q.s.
Indications:	Active immunization against rabies for Post-exposure treatment (after exposure) in 2 to < 18 years of age: Treatment after contact with animals which are rabid or suspected to be rabid or after contact with an inoculated rabies carcass.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Grant Government Medical College & Sir J.J. Group of Hospitals, , Grant Gov. Medical College & Sir J.J. Group of Hospitals, Byculla, Mumbai Maharashtra - 400008	Grant Government Medical College & Sir J.J. Group of Hospitals,	Dr. Sushant Mane
2	HCC Multispecialty Hospital LLP, 302,303,305,407, Sheetal Varsha Complex, Shivranjani Cross Road, Satellite Ahmedabad Gujarat - 380015	Parth Hospital Ethics Committee	Dr. Pranali Parekh
3	Panimalar Medical College Hospital and Research Institute, Varadharajapuram, Chennai Outer Ring Rd, Poonamallee Chennai Tamil Nadu - 600123	PMCHRI-IHEC	Dr. A Ramanath
4	Medical College and S.S.G. Hospital, Vinoba Bhave Road, Anandpura Vadodra Gujarat - 390001	Institutional Ethics Committee for Human Research	Dr. Pareshkumar Thakkar
5	All India Institute Of Medical Sciences, Raipur, Great Eastern Road, opposite Gurudwara, Tatibandh, AIIMS Campus Raipur Chhattishgarh - 492099	INSTITUTE ETHICS COMMITTEE, AIIMS RAIPUR	Dr. Atul Jindal

6	Dr. D. Y. Patil Medical College, Hospital and Research Centre, Sector 5, Nerul, Navi Mumbai Maharashtra - 400706	Institutional Ethics Committee	Dr. Amit Saxena
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In addition to point 3, the permission is subject to following condition(s):

1. The Phase III clinical trial should be conducted as per title "A randomized, open label, assessor blind, parallel, Active controlled, multicentric, bridging clinical trial to evaluate the immunogenicity and safety of three dose THRABIS vaccine (Recombinant Rabies G Protein Vaccine), administered as a simulated post exposure immunization in healthy children " [Protocol No. CRSC22001, Version 04, Dated - 20/12/2022].
2. DSMB is required to be constituted to review the safety data of phase III clinical trial.
3. The firm is required to submit the following information/documents:
 - a) Copy of 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. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.
 - b) Copy of the Insurance Certificate.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures and shall have ongoing stability program.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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