

File No: BIO/CT/25/000201
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Vaccine division)

FDA Bhawan Kotla Road,
New Delhi-110002

From:

The Drugs Controller General, India,
Central Drugs Standard Control Organization,
Directorate General of Health Services,
Government of India

To

M/s Cadila Pharmaceuticals Limited,
1389, Trasad Road, Dholka, Ahmedabad,
Gujarat (India) –382225

Subject: Permission for conducting a Phase III clinical trial titled “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”. (Study Code: CRSC25003, Version 02, date 22/04/2026)- reg.

Reference: Your Application No. BIO/CT04/FF/2025/53842 dated 31.12.2025 on the subject mentioned above.

Sir,

Please refer to your application No.: BIO/CT04/FF/2025/53842 dated 31.12.2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase III Clinical Trial of “Recombinant Rabies G Protein Vaccine 50 µg /0.5 mL” in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH
RAGHUVANSHI

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**(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)**

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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 Shrivastava of M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road Dholka (India) – 382225, Telephone No.: 2714-221481, FAX: 2714-220315, E-Mail: sanjay.s@cadilapharma.com to conduct clinical trial of the new drug or investigational new drug as per protocol number: CRSC25003, Version 02, dated 22.04.2026 in the below mentioned clinical trial sites.

CT No.: CT- 09/2026

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:

RAJEEV SINGH
RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
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:	Recombinant Rabies G Protein Vaccine 50 µg /0.5 mL	
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 NP9	0.1 µL
	Sodium Hydroxide	q.s.
Indication(s):	Active immunization against rabies for Post exposure treatment (after exposure): 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	University College of Medical Sciences (UCMS) & Guru Teg Bahadur Hospital (GTB), New Delhi	Ethics Committee - Guru Teg Bahadur Hospital, Dilshad Garden, Delhi - 110095, India ECR/510/Inst/DL/ 2014/RR-25	Dr. Manish Narang
2	All India Institute of Medical Sciences (AIIMS), Raipur, Chhattisgarh	Institutional Ethics Committee, All India Institute of Medical Sciences, Room no. 2103, 2nd Floor, South Wing, Medical College Complex, Gate No. 5, Tatibandh, GE Road, Raipur 492099, Chhattisgarh, India ECR/714/Inst/CT/2015/RR-26	Dr. Atul Jindal
3	Jawahar Lal Nehru Medical College, Ajmer. Rajasthan.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College Kala Bagh, Ajmer, Rajasthan –305001 India. ECR/1156/Inst/RJ/2018/RR-22	Dr. Jai Prakash Narayan
4	JSS Medical College, Mysuru, Karnataka	Institutional Ethics Committee JSS Medical College, JSS Medical College and Hospital, Sri Shivarathreeshwara Nagar, Mysuru - 570015, Karnataka, India ECR/387/Inst/KA/2013/RR-22	Dr. Rajani H. S

5	Belgaum Institute of Medical Sciences (BIMS), Belagavi, Karnataka	Institutional Ethics Committee, BIMS, Belagavi Institute of Medical Sciences, Dr B R Ambedkar Road, Belgaum 590001, Karnataka, India ECR/801/Inst/KA/2016/RR-25	Dr. Shailesh Patil
6	Sri Ramchandra Institute of Higher Education and Research. Chennai, Tamilnadu.	Institutional Ethics Committee, SRIHER No.1 Ramachandra Nagar Porur Chennai 600116, Tamilnadu - 600116, India ECR/203/Inst/TN/2013/RR-24	Dr. Latha Ravichandran
7	Vani Vilas Hospital, Bangalore Medical College and Research Institute (BMCRI), Bengaluru, Karnataka	Ethics Committee of Bangalore Medical College and Research Institute, Fort, Krishna Rajendra Rd, Kalasipalya, Bengaluru 560002, Karnataka, India ECR/302/Inst/KA/2013/RR-25	Dr. Shivaprakash Sosale
8	GMERS Medical College and Civil Hospital, Sola, Ahmedabad, Gujarat.	Institutional Ethics Committee, GMERS medical college, Sola Highway, Near Gujarat High court, Ahmedabad - 380061, Gujarat, India ECR/404/Inst/GJ/2013/RR-20	Dr. Nehal Patel
9	Bharati Vidyapeeth Medical College and Hospital, Pune, Maharashtra	Institutional Ethics Committee, BVDU, Bharati Hospital and Research Centre, Pune - Satara Road Dhankawadi, Pune 411043, Maharashtra, India ECR/313/Inst/MH/2013/RR-24	Dr. Sonali Palkar
10	Institute of Child Health (ICH), Kolkata, West Bengal	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresw Guha Street, Kolkata - 700017, West Bengal, India ECR/359/Inst/WB/2013/RR-24	Dr. Khaya Ghosh Uttam
11	D. Y. Patil Medical College & Hospital, Pune, Maharashtra	Ethics Committee Dy.Patil Vidyapeeth, Pimpri, Pune - 411018, Maharashtra, India ECR/361/Inst/MH/2013/RR-24	Dr. Shailaja Mane
12	Kalinga Institute of Medical Sciences (KIMS), Bhubaneswar, Odisha	Institutional Ethics Committee-KIMS, Kushabhadra campus (Campus 5) KIIT University, Patia, Bhubaneswar 751024, Odisha, India	Dr. Sonali Kar

		ECR/321/Inst/OR/2013/RR-25	
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In addition to point 3, the permission is subject to following conditions:

- I. The Phase-III clinical trial should be conducted as per approved protocol titled "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." Study Code: CRSC25003, Version 02, date 22.04.2026.
- II. Firm shall submit the copy of the clinical trial agreement between the sponsor and the clinical trial sites prior to enrolment of the subjects.
- III. To submit Ethics Committee approval for Phase III clinical trial.
- IV. Only CDL, Kasauli certified batches shall be used in proposed Phase III clinical trial in India.

Place: New Delhi
Date:

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

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