

File No: BIO/CT04/FF/2025/47160

File No: BIO/CT/24/000121

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 grant permission to M/s ZyduS Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village -Changodar, Taluka - Sanand, Dist. - Ahmedabad, Gujarat(India) – 382213, Telephone No.: 91-2717-664600 FAX: 91-2717-664600 to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: VAXI.24.001 Version No. 01 Protocol Dated 25-SEP-2024 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

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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

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licensing Authority

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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine) [PCECV ^{PM}]
Therapeutic class:	Vaccine
Dosage form:	Injection (Intramuscular/ Intradermal)
Composition:	Each lyophilized vial contains: Inactivated rabies virus (PitmanMoore Strain) Potency ≥ 2.5 IU Virus is propagated in chick embryo fibroblast cell culture and Inactivated by β-propiolactone. Excipients: Gelatin, Human Albumin, Sucrose Diluent: 1 ml Sterile Water for Injections I.P.
Presentation	Vial of lyophilized vaccine & One pack of 1 ml Sterile Water for Injections I.P.
Indication	Active immunization against rabies. 1. For Intramuscular administration, use 1 full dose (1 ml) for Pre-& Post exposure prophylaxis. 2. For Intradermal administration, use 0.1 ml per ID site for post exposure prophylaxis

Details of clinical trial sites-

S. No.	Names and Address of Clinical Trial Site	Ethics Committee Details	Name of Investigator(s) & Designation
1.	GMERS Medical College and Hospital Gotri, Gotri Road, Old TB Campus, Vadodara-390021, Gujarat	Institutional Human Ethics Committee, GMERS Medical College and Hospital Gotri, Gotri Road, Old TB Campus, Vadodara – 390021, Gujarat ECR/28/Inst/GJ/2013/RR-19	Dr. Amul N. Bhedi
2.	Hi-Tech Medical College & Hospital, Health Park, Pandra, Rasulgarh, Bhubaneswar – 751025, Odisha	Institutional Ethics Committee, Hi-Tech Medical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar – 751025, Odisha ECR/273/Inst/OR/2013/RR-20	Dr. Lisa Sarangi
3.	Nobel Hospital Pvt. Ltd.153, Magarpatta City Road, Hadapsar, Pune – 411013, Maharashtra	Noble Hospital Institutional Ethics Committee, 153, Magarpatta City Road, Hadapsar, Pune – 411013, Maharashtra ECR/259/Inst/MH/2013/RR-24	Dr. Raut Sidram Kerappa
4.	Government Medical College and Government General Hospital, Srikakulam 532001, Andhra Pradesh	Institutional Ethics Committee, Government Medical College and Government General Hospital, Srikakulam - 532001, Andhra Pradesh ECR/492/Inst/AP/2013/RR-20	Dr. K Sunil Naik

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5.	Professor, Department of Paediatrics, Institute of Medical Sciences & SUM Hospital, K8, Kalina Nagar, Ghatikia, Bhubaneswar - 751003, Odisha.	Institutional Ethics Committee, Institute of Medical Sciences & SUM Hospital, K8, Kalina Nagar, Ghatikia, Bhubaneswar – 751003, Odisha ECR/627/Inst/OR/2014/RR-20	Dr. Mrutunjay Das
6.	Marwari Hospitals, B3, Sati Joymati Road, Athgaon, Guwahati – 781008, Assam	ECRC-HEC, Marwari Hospitals, Sati Joymati Road, Athgaon, Guwahati - 781008, Assam. ECR/487/Inst/AS/2013/RR-19	Dr. Dinesh Agrawal
7.	M.K.C.G. Medical College and Hospital, Brahmapur - 760004, Ganjam, Odisha	IEC, M.K.C.G. Medical College, Brahmapur - 760004, Ganjam, Odisha. ECR/661/Inst/OR/2014/RR-21	Dr. Durga Madhab Satapathy

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

1. The clinical trial should be conducted as per approved protocol titled “A prospective, randomized, single-blind, parallel, active-controlled, multicenter, Phase IV clinical study to evaluate the long-term immunogenicity and safety of VaxiRab N compared to a WHO prequalified rabies vaccine in animal bite cases”. Protocol No.: VAXI.24.001 Version No.: 01 Dated: 25/09/2024.
2. The firm is required to constitute a DSMB to review the safety data.
3. Firm is required to submit Ethics Committee approval for Phase-IV clinical trial.
4. Only CDL, Kasauli certified vaccines already approved for manufacturing & marketing shall be used in the Phase-IV clinical trial in India.
5. Firm needs to submit validation protocol for Rapid Fluorescent Focus Inhibition Test (RFFIT) developed at M/s. Cliantha Research Ltd. in due course.

Date

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