File No: BIO/CT/19/000044
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 number: **17-06 Version No. 00** in the below mentioned clinical trial sites. dated **30-MAR-2019**.

CT No.: CT- 20/2019

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.

V G SOMANI

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

Place: New Delhi
Date: 16-SEP-2019

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Rabies Vaccine, Human, I.P.
Therapeutic class:	Vaccine
Dosage form:	Powder (Lyophilized)
Composition:	1 vial of lyophilized powder contains: Inactivated rabies virus (Pitman Moore 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: 1ml Sterilised water for Injection
Indications:	For active immunization against Rabies

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	MKCG Medical College, Berhampur, Ganjam, Odisha 760 004	Institutional Ethics Committee, MKCG Medical College, Berhampur, Ganjam, Odisha 760004 ECR/661/Inst/OR/2014/RR-17	Radha Madhab Tripathy
2	Anti Rabies Clinic, Room No. 28, S.M.S. Medical College and Attached Hospitals, First Floor, Dhanvantri OPD Block, J.L.N. Marg, Jaipur 302004, Rajasthan	The Ethics Committee, S.M.S. Medical College and Attached Hospitals, Jaipur First Floor, Dhanvantri OPD Block, S.M.S. Hospital, J.L.N. Marg, Jaipur ECR/26/Inst/Raj/2013/RR-16)	Dr. Dharmesh Kumar Sharma
3	Department of Community Medicine, Institute of Medical Sciences (IMS) & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneshwar – 751003, Odisha	Institutional Ethics Committee, IMS & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneshwar – 751003, Odisha ECR/627/Inst/OR/2014/RR-17	Dr. Epari Venkata Rao
4	Department of Community Medicine, Government Medical College and Hospital, Medical College Square, Nagpur – 440003, Maharashtra	Institutional Ethics Committee, Department of Pharmacology, Government Medical College, Nagpur – 440003, Maharashtra ECR/43/Inst/MH/2013/RR-16	Dr. Avinash Gawande
5	Department of Paediatrics. KLES Dr. Prabhakar Kore Hospital & M.R.C, NH Service Road, Nehru Nagar, Belgaum, Karnataka 590010	Institutional Ethics Committee, KLE University, JN Medical College, Nehru Nagar, Belgavi -590010, Karnataka, India ECR/211/KA/2013/RR-16	Dr. N.S. Mahanshetti

6	Department of Pediatrics, Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Baazar Ghat, Lakdikapool, Hyderabad-500004, Telangana	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad – 500059 ECR/300/Inst/AP/2013RR-16	Dr. K. Sujatha

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

I. The clinical trial should be conducted as per approved protocol titled "A prospective, randomized, single blind, parallel, active controlled, multicentre, phase IV clinical study to evaluate the long term immunogenicity and safety of VaxiRab N of M/s Cadila Healthcare Limited compared to a WHO prequalified rabies vaccine in animal bite cases" vide protocol number: 17-06 Version No. 00 dated 30-MAR-2019.
II. To submit Ethics Committee approvals of all the participating sites for clinical trial protocol before initiation of the clinical trial.
III. To submit the details of Rabies Vaccine comparator to this office before initiation of clinical trial.
IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)
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Place: New Delhi
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