File No: BIO/CT/22/000037
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.: null Fax: null e-mail: sanjaymaheshwari@zyduscadila.com, to conduct clinical trial of the new drug or investigational new drug as per Protocol No. PVRV 1001 Version No. 01 Protocol Date 21-MAR-2022 in the below mentioned clinical trial sites.

CT No.: CT- 16/2022

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: 27-JUNE-2022

VENUGOPAL G SOMANI

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

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Annexure:

Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td colspan="2">Rabies Vaccine, Human I.P. [Purified Inactivated Vero Cell Rabies vaccine – Lyophilized (PVRV)]</td></tr>
<tr><td>Therapeutic class:</td><td colspan="2">Vaccine</td></tr>
<tr><td>Dosage form:</td><td colspan="2">Liquid for IM and ID injection</td></tr>
<tr><td rowspan="9">Composition:</td><td colspan="2">Each dose of 1 ml contains:</td></tr>
<tr><td>Active Ingredients</td><td>Quantity</td></tr>
<tr><td>Inactivated rabies virus (Pitman Moore Strain) [Virus is propagated in Vero cells and inactivated by β-propiolactone]</td><td>2.5 IU</td></tr>
<tr><td>Inactive Ingredients</td><td>Quantity</td></tr>
<tr><td>Human Albumin</td><td>1%</td></tr>
<tr><td>Dextran</td><td>2%</td></tr>
<tr><td>Maltose</td><td>3%</td></tr>
<tr><td>Sucrose</td><td>NMT 6%</td></tr>
<tr><td>PBS</td><td>-</td></tr>
<tr><td>Indications:</td><td colspan="2">Active immunization against rabies.</td></tr>
</table>

Details of clinical trial sites-

S. No	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Zydus Research Centre, Survey No. 396, 403, Opp. Sarvotam Hotel, Nr. Nova Petrochemicals, Sarkhej-Bavla N.H. N. 8A, Moraiya, Ahmedabad Gujarat - 382213	Ethics Committee Sangini Hospital Santorini Square, B/H Abhishree Complex Opp. Star Bazar Nr Jodhpur Cross Roads Satellite Ahmedabad Gujarat - 380015 India [EC Reg no. ECR/147/Inst/GJ/2013/RR-19]	Dr Gaurav Jansari

In addition to point 3, the permission is subject to following condition(s):

1. The Phase I clinical trial should be conducted as per title "An open-label, single-treatment, single-period, single dose, clinical Phase 1 study to assess the safety and tolerability of Rabies Vaccine, Human I.P. Purified Inactivated Vero Cell Rabies Vaccine-Lyophilized (PVRV) of M/s. Zydus Lifesciences Ltd. (Formerly Cadila Healthcare Ltd.), India in Healthy, Adult Human Subjects." [Protocol No. PVRV 1001, Version Number: 01, Dated: 21.03.2022].
2. DSMB is required to be constituted to review the safety data of phase I clinical trial.
3. Firm is requested to submit the updated stability data (Real time & Accelerated) and ensure stability data during the clinical trial.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability program.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 27-JUNE-2022

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