File No: BIO/CT/19/000057
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 Licensing 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 Email: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: RHEV 1001 Version No. 01 Protocol Date 18-MAY-2019 in the below mentioned clinical trial sites.

**CT No.: CT- 24/2019**

1. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

2. 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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Date: 2019.11.13 14:16:59 +05'30'

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

Place: New Delhi
Date: 11-NOV-2019

**Annexure:**

**Details of new drug or investigational new drug:**

| | |
|---|---|
| Names of the new drug or investigational new drug: | Recombinant Hepatitis E Vaccine, Single Human Dose |
| Therapeutic class: | Vaccine |
| Dosage form: | Liquid |
| Composition: | Each dose of 0.5 ml contains:<br>Hepatitis E Antigen produced in E.coli cells >=30.0000 micrograms (µg) In House Specification<br>Aluminium Hydroxide gel <=1.2500 milligram (mg) I.P.<br>Produced in *E. coli* Cells |
| Indications: | For prevention of Hepatitis E virus Infection in people aged 16 years and above. |

**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, clinical Research Department, Opp Sarvotam Hotel, Sarkhej -Bavla N.H No 8A, Village: Moraiya, Ahmedabad 382213 Gujarat. | Sangini Hospital Ethics Committee 1st Floor, Santorini Square Opp. Star Bazzar Behind Abhishree Complex Near Jodhpur Cross Roads, Satellite, Ahmedabad, Gujarat- 380 015.<br><br>Registration no: (ECR/147/Inst/GJ/2013-RR16) | Dr. Taufik Momin |

In addition to point 2, the permission is subject to following conditions:

I. The clinical trial should be conducted as per approved protocol titled "An Open label, Single Treatment, Single Period, Single dose, Clinical Phase I Study to assess the safety and tolerability of Recombinant Hepatitis E Vaccine of M/s Cadila Healthcare limited, India in Healthy, Adult, Male, Human Subjects" vide protocol number: RHEV 1001, Version No.: 01, Dated 18-May -2019.
II. Only CDL, Kasauli certified batches shall be used in the clinical trial.

V G SOMANI

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