File No: BIO/CT/19/000054
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)-382213Telephone No.: null FAX: null E Mail: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: HAV 1001, Version No. 01 Protocol Dated 18-MAY-2019 in the below mentioned clinical trial sites.

CT No.: CT- 23/2019

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: 2019.11.06 18:51:22 +05'30'

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

Place: New Delhi
Date: 06-NOV-2019

Annexure:

Details of new drug or investigational new drug:

Names of the new drug or investigational new drug:	Inactivated Hepatitis A Vaccine (Adsorbed) I.P. –Single Human Dose
Therapeutic class:	Vaccine
Dosage form:	Liquid
Composition:	Each dose of 1ml contains: Hepatitis A Antigen=50.0000 IU IH Aluminium Hydroxide<=1.2500 milligram (mg) I.P. RGSB Strain of Hepatitis A virus propagated in MRC-5 cells inactivated by formaldehyde.
Indications:	For the prevention of disease caused by Hepatitis A Virus (HAV) in person 12months of age and older.

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 Moraiya, Ahmedabad.	Sangini Hospital Ethics Committee 1st Floor, Santorini Square Opp. Star Bazzar Behind Abhishree Complex Near Jodhpur Cross Roads, Satellite, Ahmedabad, Gujarat 380015 Registered (ECR/147/Inst/GJ/2013-RR16)	Dr Taufik Momin

In addition to point 3, 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 Inactivated Hepatitis A Vaccine (Adsorbed) I.P. of M/s Cadila Healthcare limited, India in Healthy, Adult, Male, Human Subjects” vide protocol number: HAV1001 Version No. 01 dated 18-05-2019 with the condition that both the genders should be part of the study.

II. Only CDL, Kasauli certified batches shall be used in the clinical trial.

V G SOMANI

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(Dr. V. G. Somani)
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