

File No: BIO/CT/22/000070
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 M/s Zydus Lifesciences Ltd. (Formerly Cadila Healthcare Limited), Zydus Corporate Park, Scheme No. 63, Survey No. 536, Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad, Gujarat (India) - 382481, Telephone No.: 79-71800000 FAX: 79-48041500 E-Mail: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: Project No. 22-06 , version 01 dated 07.10.2022** in the below mentioned clinical trial sites.

CT No.: CT- 27/2022

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.
4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Date: 29-NOV-2021
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Recombinant Hepatitis E Vaccine (Adsorbed)		
Therapeutic class:	Vaccine (Recombinant)		
Dosage form:	Liquid for injection by intramuscular (IM) route in three doses (day 0, 30 & 180)		
Composition:	Each 0.5 mL Contains:		
	Hepatitis E Protein (Produced in <i>E.coli</i> cells)		30 mcg
	Aluminium content		≤ 1.25 mg
	2-Phenoxyethanol		2.5 mg
Indications:	For prevention of disease caused by Hepatitis E Virus (HEV) in person 16 years of age and above		

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Maharaja Agrasen Hospital Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur - 302039, Rajasthan	Institutional Ethics Committee, Maharaja Agrasen Hospital Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur - 302039, Rajasthan ECR/1222/Inst/RJ/2019	Dr. Deepak Sharma
2	Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, Bopal-Ghuma Road, Bopal, Ahmedabad - 380058, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, Bopal-Ghuma Road, Bopal, Ahmedabad - 380058, Gujarat ECR/1565/Inst/GJ/2021	Dr. Chintan Patel
3	Vedant Multispeciality Hospital, GP 83, Opp. Rotary Club Sambhaji nagar, MIDC, Chinchwad, Pune - 411019, Maharashtra.	Institutional Ethics Committee, Vedant Multispeciality Hospital, GP 83, Sambhaji nagar, MIDC Chinchwad, Pune - 411019, Maharashtra (ECR/1426/Inst/MH/2020)	Dr. Abhishek M. Karmalkar
4	Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow -226014, Uttar Pradesh	Institutional Ethics Committee, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow -226014, Uttar Pradesh ECR/16/Inst/UP/2013/RR-20	Dr. Amit Goel
5	Institute of Post Graduate Medical Education and Research (IPGMER) and Seth Sukhlal Karnani Memorial (SSKM) Hospital, 244, A.J.C. Bose Road, Kolkata -700020, West Bengal	PGMER Research Oversight Committee, IPGMER, 244, Acharya J.C. Bose Road, Kolkata -700020, West Bengal ECR/35/Inst/WB/2013/RR-19	Dr. SK Mahiuddin Ahammed

6	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Dhanvantari Nagar, Puducherry - 605006	Institutional Ethics Committee Intervention Studies, JIPMER, Dhanvantari Nagar, Puducherry - 605006	Dr. Pazhanivel Mohan
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In addition to point 4, the permission is subject to following condition(s):

- I. The clinical trial should be conducted as per title "A prospective, randomized, two-arm, parallel, placebo-controlled, multicentre, superiority, phase II clinical trial to evaluate the immunogenicity and safety of Recombinant Hepatitis E Vaccine (Adsorbed) of M/s. Zydus Lifesciences Limited in healthy subjects" vide Protocol No. Project No.: 22-06, Version 01 dated 07.10.2022.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. The firm is required to submit report on animal challenge studies as per WHO Technical Report Series, No. 1016.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability program.
- V. Firm is required to submit updated stability data (accelerated & real time) of Drug substances & Drug product and ensure its stability during clinical trial.
- VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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