File No: BIO/CT/21/000032

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 Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:varma.bhupathiraju@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per protocol no. BECT067/HepA-Phase-I/CTP-01, Protocol Version 1.0, dated 27-Jan-.2021 in the below mentioned clinical trial sites.

CT No.: CT- 38/2021

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.

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2021.10.21 16:00:33 +05'30'

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

Date: 21-Oct-2021
Place: New Delhi

Stamp

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Inactivated Hepatitis A Vaccine (Adsorbed)	
Therapeutic class:	Vaccine	
Dosage form:	Solution for Injection by Intramuscular route	
Composition:	Each 1.0mL of Vaccine contains:	
	Ingredients	**Quantity**
	Inactivated Hepatitis A Virus Antigen	50 IU
	Aluminium Hydroxide gel	0.45mg
	Sodium borate	70mcg
	2-Phenoxy ethanol	5.55mg
	Sodium chloride	q.s.
Indications:	For active immunization against infection caused by Hepatitis A virus.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Maharaja Agrasen perspeciality Hospital Central Spine, grasen Aspatal Marg, Sector 7, Vidya Nagar, Jaipur, Rajasthan–302039, India	Institutional Ethics Committee, Maharaja Agrasen perspeciality Hospital Central Spine, grasen Aspatal Marg, Sector 7, Vidya Nagar, Jaipur, Rajasthan–302039, India.[ECR/1222/Inst/RJ/2019]	Dr Prabhat Kumar Sharma

In addition to point 4, the permission is subject to following condition(s):

I. The Phase I clinical trial should be conducted as per protocol titled ""A prospective open label single arm phase-I study to assess the safety, tolerability, reactogenicity and immunogenicity of a single intramuscular dose of BE's indigenously developed inactivated Hepatitis A vaccine (adsorbed) administered to 18-45 years old healthy human adults.[Protocol no: BECT067/HepA-Phase-I/CTP-01, Protocol Version 1.0, dated 27.01.2021].

II. The firm is required to comply & submit following data/documents:
   a. Copy of the Insurance Certificate.
   b. Details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator.
   c. The manufacturing permission in Form CT-11 for clinical trial purpose of Inactivated Hepatitis A Vaccine (Adsorbed).

III. DSMB should be constituted for review of the safety data of the clinical trial

IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.

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

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Date: 2021.10.21 16:00:44 +05'30'

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