File No: BIO/CT/24/000041
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002
Date:

To,

M/s Human Biologicals Institute,
(A division of Indian Immunologicals Limited),
Sy. No. 281-284 & 321, Biotech Park Phase-III,
Karkapatla Village, Markook Mandal,
Siddipet District – 5002281, Telangana, India.

Subject: Permission for conducting a clinical trial titled "An open label single centric Phase I clinical trial to evaluate the safety and immunogenicity of Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P. of HBI when administered in two groups of healthy male subjects" [Protocol Number: HBI/JE1/24/02.1.1, Version: 01; Amendment: 01, Dated: 08 July 2024] - regarding.

Reference: Your Application No. BIO/CT04/FF/2024/42338 dated 02-APR-2024 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2024/42338 dated 02-APR-2024, received by this office on the above subject. Please find enclosed herewith permission to conduct phase I clinical trial of "Japanese Encephalitis vaccine Inactivated (Adsorbed, Human) I.P." in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs and Cosmetics Rules, 1945 and communication of Central Licencing Authority.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

File No: BIO/CT/24/000041
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 Human Biologicals Institute (A division of Indian Immunologicals Limited), Survey No. 281-284 & 321, Biotech Park Phase-III, Karkapatla Village, Markook Mandal, Siddipet District – 5002281, Telangana, India; Telephone No.: 04023000211, FAX: 04023000512, E-mail: IILRA@INDIMMUNE.COM to conduct Phase-I clinical trial of the new drug or investigational new drug as per Protocol Number: HBI/JE1/24/02.1.1, Version: 01; Amendment: 01, Dated: 08 July 2024 in the below mentioned clinical trial sites.

CT No.: CT- 14/2024

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.

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular Injection	
Composition:	Each dose of 0.5 mL contains:	
	Name of Ingredients	**Quantity per dose**
	Active Ingredient	
	Purified Inactivated Japanese Encephalitis Virus (Strain Beiging-1, propagated in Vero Cells) protein	≥ 6 µg
	Inactive Ingredients	
	Aluminium hydroxide gel equivalent to Al^{+++} content	≤ 1.25 mg
	Thiomersal	0.01 % w/v
	Phosphate Buffer Saline (PBS)	q.s.
Indication(s):	Prevention against Japanese Encephalitis Infection.	

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	V. S. General Hospital E-Ward, Neuro Trauma Building, Nr. Ellisbridge, Paldi, Ahemedabad-380006, Gujarat, India	Shrey Hospital Institutional Ethics Committee, Shrey Hospital Private Limited 270/B/5 Near AMCO Bank, Stadium Circle Navrangpura, Ahmedabad, Gujarat – 380009, India. [ECR/1302/Inst/GJ/2019]	Dr. Devang Rana

In addition to point 3, the permission is subject to following conditions:

I. The clinical trial should be conducted as per the protocol titled "An open label single centric Phase I clinical trial to evaluate the safety and immunogenicity of Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P. of HBI when administered in two groups of healthy male subjects" [Protocol Number: HBI/JE1/24/02.1.1, Version: 01; Amendment: 01, Dated: 08 July 2024].
II. Only CDL, Kasauli certified batches shall be used in Phase-I clinical trial.
III. To submit Ethics Committee approval for Phase-I clinical trial.
IV. To submit Insurance Certificate for Phase-I Clinical trial.

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: