

File No: BIO/CT/21/000038
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 Mr. Rajesh Sharma of M/s Urihk Pharmaceutical Private Limited, 602-603, Sai Samarth Business Park, Near Wasan Motors, Deonar Village Road, Deonar, Govandi (East) Mumbai (India) - 400088 Telephone No.: 7208644515 FAX: 022-49743286 E-Mail : REGULATORY@URIHKPHARMA.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: URI/HEV/CT-01/21 Version No. 01 Protocol Date 24-FEB-2021 in the below mentioned clinical trial sites.

CT No: CT-14/2021

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.

Place: New Delhi
Date: 18-MAY-2021

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

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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Recombinant Hepatitis E Vaccine (<i>E. Coli</i>)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid Injection through Intramuscular route of administration	
Composition:	Each dose of 0.5 ml vaccine contains:	
	Name of Active ingredient	Quantity
	HEV239 protein [Expressed in <i>E. Coli</i> ER2566 by the expression vector pTO-T7 containing HEV239 gene]	30.00 µg
	Name of Inactive ingredients	Quantity
	Aluminum hydroxide	0.800 mg
	Sodium chloride	4.250 mg
	Thiomersal	0.025mg
	Disodium hydrogen phosphate	0.144mg
	Potassium dihydrogen phosphate	0.057mg
	Potassium chloride	0.010mg
	Water for injection	q.s.
Indications:	For active immunization against infection caused by Hepatitis E Virus	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Sai Sneh Hospital and Diagnostic Centre, Opp PMT Bus Depot, Pune Satara Rd, Katraj, Pune, Maharashtra, 411046	Institutional Ethics Committee of Sai Sneh Hospital and Diagnostic Centre Address: Opp PMT Bus Depot, Pune- Satara Rd, Katraj, Pune, Maharashtra, 411046 [EC Registration No. ECR/989/Inst/MH/2017/RR-20]	Dr. Sumeet Sunil Jagtap
2	Institute of Medical Sciences (IMS) & SUM Hospital (Faculty of Medical Sciences), Siksha 'O' Anusandhan (Deemed to be University), K8, Kalinga Nagar, Ghatikia Bhubaneswar, Odisha, 751003	Institutional Ethics Committee, IMS) & SUM Hospital, K8, Kalinga Nagar, Ghatikia Bhubaneswar, Odisha, 751003, [EC Registration No: ECR/627/Inst/OR/2014/RR-20]	Dr. Samir Sahu
3	Jawaharlal Nehru (JN) Medical College and Hospital Aligarh Muslim University, Civil Line, Koil, Aligarh, Uttar Pradesh, 202002	Institutional Ethics Committee, Jawaharlal Nehru Medical College and Hospital Aligarh Muslim University, Civil Line, Koil, Aligarh, Uttar Pradesh, 202002 [EC Registration No: ECR/1418/Inst/UP/2020]	Dr. M. Uwais Ashraf

4	VGM Hospital, 2100, Trichy Road, Rajalakshmi Mills Stop, Singanallur Coimbatore, Tamil Nadu, 641005	Institutional Ethics Committee, VGM Hospital, 2100, Trichy Road, Rajalakshmi Mills Stop, Singanallur Coimbatore, Tamil Nadu, 641005 [EC Registration No: ECR/217/Inst/TN/2013/RR-20]	Dr. VG. Mohanprasad
5	Department of Medicine, B.J. Government Medical College and Sassoon General Hospitals, Sassoon Road, Somwar Peth, Pune, Maharashtra, 411001	Institutional Ethics Committee, B.J. Government Medical College and Sassoon General Hospitals, Sassoon Road, Somwar Peth, Pune, Maharashtra, 411001 [EC Registration No: ECR/280/Inst/Maha/2013/RR-19]	Dr. RohidasBorse
6	GMERS Medical College and Civil Hospital Sola. Nr. Gujarat High Court, S. G. Highway, Sola, Ahmedabad, Gujarat, 380060	Institutional Ethics Committee GMERS Medical College & Civil Hospital Sola, Department of Pharmacology. 4th Floor College Building. Nr. Gujarat. High Court. S.G. Highway Sola, Ahmedabad, Gujarat, 380060 [EC Registration No: ECR/404/1nst/GJ/2013/RR-20]	Dr. Parul Bhatt

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

- I. The clinical trial should be conducted as per approved protocol titled "A Prospective, Randomized, Double Blind, Placebo controlled Phase III, Multicenter Study to evaluate the Immunogenicity and Safety of Recombinant Hepatitis E Vaccine in Healthy Adults & Adolescents" [Protocol: URI/HEV/CT-01/21, Version 01 dated 24.02.2021]".
- II. The clinical trial permission issued vide no. CT-17/2019 to M/s Wockhardt Ltd. to conduct Phase-III Clinical trial of Recombinant Hepatitis E Vaccine stands cancelled.
- III. Firm is required to submit following information/documents:
 - a. Legal Affidavit declaring that the information about study drug as mentioned in Investigators Brochure is correct and based on available facts.
 - b. Receipt of payment of additional fees of Rs. One Lakh as prescribed in Sixth Schedule of New Drugs and Clinical Trials Rules, 2019 should be submitted before initiation of trial.
 - c. Copy of Insurance Certificate before initiation of subject trial.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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Place: New Delhi
Date: 18-MAY-2021

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

File No: BIO/CT/21/000038
FORM CT-17

(See rules 68, 69, 70, 71 and 72)

LICENCE TO IMPORT NEW DRUG FOR THE PURPOSE OF CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS

License Number: TL/BIO/21/000014

The Central Licencing Authority hereby grants licence to M/s Urihk Pharmaceutical Private Limited 602-603, Sai Samarth Business Park, Near Wasan Motors, Deonar Village Road, Deonar, Govandi (East) Mumbai - 400088 Maharashtra to import new drug or investigational new drug for conduct of clinical trial ~~or bioavailability or bioequivalence study~~ as per protocol number URI/HEV/CT-01/21, Version 01 dated 24.02.2021 in the below mentioned clinical trial sites ~~or bioavailability or bioequivalence study centre~~.

S. No.	Name of the new drug to be imported	Therapeutic class of new drug	Quantity to be imported
1.	Recombinant Hepatitis E Vaccine (E. Coli)	Recombinant Vaccine	450 Mono Cartons (0.5ml PFS per mono carton)
2.	Placebo	placebo	450 Mono Cartons (0.5ml PFS per mono carton)

2. This license is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.
3. This license shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
4. Details of overseas manufacturer and manufacturing site under this license.

S. No.	Name and address of manufacturer	Name and address of manufacturing site
1.	M/s Xiamen Innovax Biotech Co., Ltd, No. 130-1, Xinyuan Road, Haicang District, Xiamen, Fujian (China) - 361022 Telephone No.: 86-592-6536555-8601 FAX: 86-592-653-6567	M/s Xiamen Innovax Biotech Co., Ltd, No. 130-1, Xinyuan Road, Haicang District, Xiamen , Fujian (China) - 361022 Telephone No.: 86-592-6536555-8601 FAX: 86-592-653-6567

5. The licensee shall maintain the record imported new drug or investigational new drugs [As per Annexure].

Place: New Delhi
Date: 18-MAY-2021

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Stamp

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Date: 2021.05.19 11:36:28 +05'30'

Annexure:

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4	VGM Hospital, 2100, Trichy Road, Rajalakshmi Mills Stop, Singanallur Coimbatore, Tamil Nadu, 641005	Institutional Ethics Committee, VGM Hospital, 2100, Trichy Road, Rajalakshmi Mills Stop, Singanallur Coimbatore, Tamil Nadu, 641005 [EC Registration No: ECR/217/Inst/TN/2013/RR-20]	Dr. VG. Mohan prasad
5	Department of Medicine, B.J. Government Medical College and Sassoon General Hospitals, Sassoon Road, Somwar Peth, Pune, Maharashtra, 411001	Institutional Ethics Committee, B.J. Government Medical College and Sassoon General Hospitals, Sassoon Road, Somwar Peth, Pune, Maharashtra, 411001 [EC Registration No: ECR/280/Inst/Maha/2013/RR-19]	Dr. Rohidas Borse
6	GMERS Medical College and Civil Hospital Sola. Nr. Gujarat High Court, S. G. Highway, Sola, Ahmedabad, Gujarat, 380060	Institutional Ethics Committee GMERS Medical College & Civil Hospital Sola, Department of Pharmacology. 4th Floor College Building. Nr. Gujarat. High Court. S.G. Highway Sola, Ahmedabad, Gujarat, 380060 [EC Registration No: ECR/404/Inst/GJ/2013/RR-20]	Dr. Parul Bhatt