File No: BIO/CT/24/000101
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 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 Phase-IV clinical trial of the new drug or investigational new drug as per [Protocol No.: CRNI/CTP/24/07 Version No. 2 Protocol Date 15-Oct-2024 in the below mentioned clinical trial sites.

CT No.: CT- 15/2024

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.

RAJEEV SINGH RAGHUVANSHI

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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:	Recombinant Hepatitis E Vaccine (E. Coli)	
Therapeutic class:	Vaccine	
Dosage form:	Pre-Filled Syringe (0.5ml)	
Composition:	Each dose of 0.5 mL contains	
	Name of Ingredients	**Quantity**
	Active Ingredient	
	Recombinant HEV239 protein	30 µg
	Inactive ingredient	
	Aluminium hydroxide	0.800 mg
	Sodium chloride	4.250 mg
	Thiomersal	0.025 mg
	Disodium hydrogen phosphate	0.144 mg
	Potassium dihydrogen phosphate	0.057 mg
	Potassium chloride	0.010 mg
	Water for injection	q.s
Indication(s):	For active immunization against infection caused by Hepatitis E Virus for age group of 18 years to 65 years.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Sites	Ethics Committee details	Name of Principal Investigators
1	Dr. D.Y. Patil Vidyapeeth, C/o Vice Chancellor, Dr. D.Y. Patil Vidyapeeth, Pune, Sant Tukaram Nagar, Pimpri, Pune Maharashtra - 411018	Ethics Committee, Dr. D. Y. Patil Vidyapeeth Dr. Pimpri, Pune, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra 411018. [ECR/361/Inst/MH/2013/RR-19]	Dr Srikanth Tripathy
2	LLR Hospital, GSVM Medical College, Swaroop Nagar Kanpur Uttar Pradesh - 208002	Ethics Committee GSVM Medical College, Kanpur, Uttar Pradesh, India [ECR/680/Inst/UP/2014/RR-20]	Dr Richa Giri
3	All India Institute of Medical Sciences, Phulwarisharif, Patna Bihar - 801507	Institutional Ethics Committee, All India Institute of Medical Sciences, Phulwarisarif, Patna, Bihar [ECR/1387/Inst/BR/2020]	Dr Sanjay Pandey

4	Bhate Hospital, Belagavi, Karnataka Belgavi Karnataka - 590002	Ethics Committee Jeevan Rekha Hospital, Dr. B. R. Ambedkar Road, opp. Civil Hospital, Belagavi, Karnataka - 590002 [ECR/1242/Inst/KA/2019 RR-22]	Dr Amit S Bhate
5	Sai Medicity Pvt. Ltd., B-33,33-52, Rohit Nagar Varanasi Uttar Pradesh - 221005	Ethics Committee of Sai Medicity Pvt. Ltd., B33/33-52, Rohit Nagar, Naria, Varanasi, Uttar Pradesh - 221005 [ECR/1660/Inst/UP/2022]	Dr Vivekanand Rai

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, Multicentre, Single Arm, Phase-IV Study to evaluate the Safety and Immunogenicity of Recombinant Hepatitis E Vaccine (E. Coli) in Healthy Adults. [Protocol Number: CRNI/CTP/24/07, Version Number: 02; dated 15/Oct/2024].
II. To submit Ethics Committee approval for proposed Phase-IV Clinical trial.
III. To submit Insurance Certificate for proposed Phase-IV Clinical trial

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

Place: New Delhi
Date:

File No: BIO/CT/24/000101
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 Urihk Pharmaceutical Private Limited,
602-603, Sai Samarth Business Park, Near
Wasan Motors,Deonar Village Road, Deonar,
Govandi (East) Mumbai (India) – 400088

Subject: Permission for conducting a clinical trial titled "A Prospective, Multicentre, Single Arm, Phase-IV Study to evaluate the Safety and Immunogenicity of Recombinant Hepatitis E Vaccine (E. Coli) in Healthy Adults. [Protocol Number: CRNI/CTP/24/07, Version Number: 02; dated 15/Oct/2024].- regarding.

Reference: Your Application No. BIO/CT04/FF/2024/44890 dated 13-AUG-2024 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2024/44890 dated 13-AUG-2024, received by this office on the above subject. Please find enclosed herewith permission to conduct phase IV clinical trial of "Recombinant Hepatitis E Vaccine (E. Coli)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI

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