File No: BIO/CT/24/000157
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

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

To

M/s Translational Health Science and Technology Institute,
NCR Biotech Science Cluster, 3rd Milestone,
Faridabad-Gurgaon Expressway,
Faridabad, Haryana (India) – 121001

Subject: Permission for conducting a clinical trial titled "A randomized, Phase 1, single-centre, observer-blind, active-controlled, 3-arm study to evaluate the safety, tolerability and immunogenicity of a single administration of TETRA^{LITE}, a novel adjuvanted influenza vaccine, in healthy participants aged 18 to 50 years" [Protocol number: DBT/BRIC-THSTI/001/2024, Version 1.1 dated 03-April-2025.

Reference: Your Application No. BIO/CT04/FF/2024/46683 dated 05-Dec-2024 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2024/46683 dated 05-Dec-2024, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Inactivated Influenza vaccine + LiteVax Adjuvant" 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
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.12.09 10:25:20 +05'30'

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

File No: BIO/CT/24/000157
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. Translational Health Science and Technology Institute, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurgaon Expressway Faridabad, Haryana (India) – 121001, Telephone No. 91-129-2876300, FAX: 91-129-2876402 to conduct clinical trial of the new drug or investigational new drug as per protocol number: DBT/BRIC-THSTI/001/2024, Version 1.1 dated 03-April-2025.

CT No.: CT- 24/2025

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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Date: 2025.12.09 10:25:28 +05'30'

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

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) [VaxiFlu™-4] + LiteVax Adjuvant (LVA)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Liquid Injection for intramuscular administration</td></tr>
<tr><td>Composition:</td><td>Preparation of Vaccine for Phase-I clinical study:
• Arm 1: VaxiFlu™-4* [Full dose (15 µg) of each strain].
• Arm 2: TETRA^{LITE} vaccine [1/5th dose (3 µg) of VaxiFlu™ -4* + 0.5 mg LVA]#.
• Arm 3: TETRA^{LITE} vaccine [1/5th dose (3 µg) of VaxiFlu™ -4* + 1 mg LVA]#.

Composition of LiteVax Adjuvant (LVA) per mL:
<table><tr><th>Component</th><th>Quantity / mL</th></tr><tr><td>Squalane content</td><td>40 mg/mL</td></tr><tr><td>Carbohydrate fatty acid Mono Sulphate Ester (CMS)</td><td>20 mg/mL</td></tr><tr><td>Polysorbate 80</td><td>20 mg/mL</td></tr><tr><td>Dulbecco's Phosphate Buffered Saline</td><td>Q.S. to 1mL</td></tr></table>* WHO recommended strains.
0.9% NaCl solution to be used as Diluent.</td></tr>
<tr><td>Indication(s):</td><td>Prevention of Influenza.</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and address of clinical trial site	Ethics committee details	Name of Principal Investigator
1.	Department of Pulmonary Medicine, Christian Medical College, Vellore, Ranipet Campus, Ranipet-632517, Tamil Nadu, India.	Institutional Review Board, Christian Medical College, Thorapadi post Bagayam Vellore, Tamil Nadu-632012, India **[ECR/326/Inst/TN/2013/RR-24]**	Dr. D. J. Christopher, Senior Professor, Department of Pulmonary Medicine, CMC Vellore.

In addition to point 3, the permission is subject to following condition(s):

1. The Phase I clinical trial should be conducted as per approved protocol titled "A randomized, phase I, single-centre, observer-blind, active-controlled, 3-arm study to evaluate the safety, tolerability and immunogenicity of a single administration of

TETRA^{LITE}, a novel adjuvanted influenza vaccine, in healthy participants aged 18 to 50 years" (Protocol number: DBT/BRIC-THSTI/001/2024 Version 1.1 dated 03.04.2025).

2. Characterization data of impurities arising from the CMS synthesis and purification and the characterization data of CMS isomers for LiteVax adjuvant (LVA) to be provided for the late-stage clinical and commercial batches of the LVA.
3. Information regarding any change in the manufacturing process or additional purification step (if any) for LiteVax Adjuvant (LVA) to be intimated to this office as PAC-CT application in SUGAM portal.
4. As part of stability testing, degradation products of CMS in LiteVax Adjuvant (LVA) to be identified and quantified during storage for the late-stage clinical and commercial batches of the LVA and same to be provided.
5. LiteVax Adjuvant (LVA) should have required stability during the Phase-I clinical trial administration.
6. The firm is required to constitute a DSMB to review the safety data.
7. The formulation intended to be used in Phase-I clinical trial should be manufactured under GMP conditions.
8. Only CDL, Kasauli certified batches should be used in the clinical trial.
9. To submit Ethics Committee approval for Phase-I clinical trial.
10. To submit Insurance Policy 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**:**