File No: BIO/CT/23/000002
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Vaccine 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 M/s. Serum Institute of India Pvt. Ltd S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114,168-170 (M), Hadapsar, Pune 411028 Telephone No.: 020-26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail:parag.nagarkar@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: YWF:05, Version 02 dated 31.05.2023.

CT No.: CT- 07/2026

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: 2026.05.20 10:38:00 +05'30'

Place: New Delhi
Date:

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

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Yellow Fever Vaccine (Live) (I.P)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Lyophilized formulation supplied with sterile water for Injection as diluent.</td></tr>
<tr><td>Composition:</td><td>After reconstitution, each dose of 0.5 mL contains:
<table>
<tr><th>Name of ingredients</th><th>Quantity</th></tr>
<tr><td>Yellow Fever Virus 17D-213 strain* (live, attenuated</td><td>Not less than 1000 IU (3 log10 IU)/dose</td></tr>
<tr><td>Gelatin</td><td>0.5 %</td></tr>
<tr><td>D-Sorbitol</td><td>1.0 %</td></tr>
<tr><td>L-Histidine</td><td>0.04 %</td></tr>
<tr><td>L- Alanine</td><td>0.02 %</td></tr>
<tr><td>Tricine</td><td>0.06 %</td></tr>
<tr><td>L-Arginine</td><td>0.32 %</td></tr>
<tr><td>Lactalbumin Hydrolysate</td><td>0.07 %</td></tr>
<tr><td>Phosphate buffered saline (PBS)**</td><td>q.s.</td></tr>
</table>
* Propagated in Specific Pathogen Free hen’s eggs
** Phosphate buffered saline (PBS) contains Sodium chloride (NaCl), Potassium chloride (KCl), Potassium dihydrogen phosphate (KH2PO4), Disodium hydrogen phosphate dihydrate (Na2HPO4. 2H2O</td></tr>
<tr><td>Indication(s):</td><td>For active immunization of person 9 months of age and older for prevention of Yellow Fever.</td></tr>
</table>

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	Department of Pharmacology, Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences (PGIMS), Medical Rd, Rohtak, Haryana 124001 India	Institutional Ethics Committee, Pt. B. D. Sharma Post Graduate Institute of Medical Sciences (PGIMS), Directorate Office, Rohtak, Haryana – 124001 ECR/293/Inst/HR/2013/RR-24	Dr. Savita Verma

2.	Department of Pediatrics, 1st floor, J.S.S Medical College & Hospital, Mahathma Gandhi Road -570004 Mysore, Karnataka. India.	Institutional Ethics Committee, JSS Medical College, JSS Hospital, Sri Shivarathreeshwara Nagara, Mysuru, Karnataka -570015 India. ECR/387/Inst/KA/2013/RR-22	Dr. Mandyam Dhati Ravi

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

I. The proposed clinical trial should be conducted as per protocol titled "A Phase III, Multicenter, Double blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL® in Healthy Children" vide Protocol No.: YWF:05 Version 02 dated 31.05.2023.

II. The clinical trial sites should be notified to the concerned authority of the Yellow fever vaccination programme.

III. DSMB will be constituted to review the safety data for all participants.

IV. Only CDL, Kasauli tested and certified consistency batch shall be used in proposed Phase-III clinical trial

V. To submit the ongoing real time stability data and stability failures, if any, shall be informed to this office forthwith along with root cause analysis.

VI. Submit Ethics Committee approval for Phase-III clinical trial.

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