File No: BIO/CT/22/000153

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 Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road., Hadapsar, Pune, Maharashtra (India) – 411028 Telephone No.: 020-26602113, 26602378, 26602978 FAX: 020-26993945, 26993921 E-Mail: drpsk@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug as per protocol number YWF: 04 Version: 03 dated 17 Oct 2023 in the below mentioned clinical trial sites.

CT No.: CT- 15/2023

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:

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

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Yellow Fever Vaccine (Live) I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized formulation supplied with sterile water for Injection as diluent (10 dose presentation in vials)	
Composition:	After reconstitution, each dose of 0.5 mL contains (10 Dose presentation):	
	Name of ingredients	**Quantity**
	Yellow Fever Virus 17D-213 strain* (live, attenuated)	Not less than 1000 IU (3 log10 IU)/dose
	Gelatin	0.5 %
	D-Sorbitol	1.0 %
	L-Histidine	0.04 %
	L-Alanine	0.02 %
	Tricine	0.06 %
	L-Arginine	0.32 %
	Lactalbumin Hydrolysate	0.07 %
	Phosphate buffered saline (PBS)**	q.s.
	** Propagated in Specific Pathogen Free hen's eggs* *** Phosphate buffered saline (PBS) contains Sodium chloride (NaCl), Potassium chloride (KCl), Potassium dihydrogen phosphate (KH_2PO_4), Disodium hydrogen phosphate, dihydrate (Na_2HPO_4, $2H_2O$)*	
Indication(s):	For active immunization of ≥18 years of age for prevention of Yellow Fever	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Clinical Trial and Training Centre, I-Block, Ground floor, Mahatma Gandhi Medical College and Research Institute, Pondicherry - Cuddalore Rd, ECR, Pillayarkuppam, Puducherry 607402	Institutional Human Ethics Committee, Mahatma Gandhi Medical College Research Institute No.45-A, Pondy-Cuddalore Main Road Pillaiyarkuppam Puducherry - 607402 [ECR/451/Inst/PO/2013/RR-19]	Dr Balaji More
2	Hakeem Abdul Hameed centenary Hospital (HAHCH), Hamdard Institute of Medical Sciences and Research (HIMSR) Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062 India Along with Center for Health Research and Development (CHRD),	Institutional Ethics Committee HIMSR And Associated HAH Centenary Hospital Guru Ravidas Marg Hamdard Nagar South West Delhi, Delhi - 110062 India [ECR/1597/Inst/DL/2021]	Dr Vineet Jain

	Society for Applied Studies (SAS), 680, Gali No. 5, Nai Basti, Devli Gaon, New Delhi		
3	King Edward Memorial Hospital Research Centre, Shirdi Sai Baba Hospital, Vadu Budruk, Taluka Shirur, Pune. MAHARASHTRA-412216 India	KEM Hospital Research Centre Ethics Committee, TDH Building, 3rd Floor, Room No -303, Sardar Moodliar Road, Rasta Peth, Pune, Maharashtra - 411011 [ECR/272/Inst/MH/2013/RR-22]	Dr. Anand Kawade

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

1. The Phase II / III clinical trial should be conducted as per approved protocol titled “A Phase II/III, Multicenter, Double Blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL® in Adults (Protocol No.: YWF: 04, Version: 03 dated 17 Oct. 2023)”.
2. Firm is required to constitute a DSMB to review the safety data.
3. Firm shall submit Phase II study report along with DSMB review report for approval before initiation of Phase III.
4. Adverse events of special interest (AESI) of Yellow Fever vaccine to be included in the Patient information sheet.
5. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
6. Only CDL, Kasauli certified batches shall be used in the clinical trial.
7. Firm is required to submit Ethics Committee approval for clinical trial.

Place: New Delhi
Date:

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