File No: BIO/CT/23/000007

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 Dengusiil-02 Version No. 2.0 Dated 24.05.2023 in the below mentioned clinical trial sites.

CT No.: CT- 14/2023

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:

RAJEEV SINGH RAGHUVANSHI

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

CDSCO CDSCO
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA
सत्यमेव जयते

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Dengue Tetravalent Vaccine (Live, Attenuated)	
Therapeutic class:	Vaccine	
Dosage form:	Freeze-dried formulation supplied with sterile water for Injection as a diluents (Single Dose presentation)	
Composition:	Each dose of 0.5 mL of vaccine contains:	
	Name of ingredients	**Quantity**
	Dengue serotype 1	NLT 2.5 $\log_{10}$ PFU
	Dengue serotype 2	NLT 2.5 $\log_{10}$ PFU
	Dengue serotype 3	NLT 2.5 $\log_{10}$ PFU
	Dengue serotype 4	NLT 2.5 $\log_{10}$ PFU
	Sucrose	5% w/v
	Glycine	5% w/v
	Minimum essential medium (MEM)	q.s.
Indication(s):	Prevention of Dengue Fever	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Hamdard Institute of Medical Sciences and Research with Centre for health Research and Development (CHRD), Society for Applied Studies (SAS), Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062, India	Jamia Hamdard Institutional Ethics Committee, Hamdard Nagar, New Delhi, South Delhi – 110062, India [ECR/1597/Inst/DL/2021]	Dr. Sunil Kohli
2	Kalinga Institute of Medical Sciences, Kushabhadra Campus, KIIT Campus, 5, KIIT Road, Patia, Bhubaneswar, Odisha 751024, India	Institutional Ethics Committee-KIMS, Kalinga Institute of Medical Sciences, Khushabhadra Campus 5, KIIT University, Patia Bhubneswar, Khorda, Orissa – 751024, India [ECR/321/Inst/OR/2013/RR-20]	Dr Sonali Kar
3	KEM Hospital Research Centre, 489, Rasta Peth, Sardar Moodliar Road, Pune, Maharashtra 411011, India	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth, Pune411011, Maharashtra, India. [ECR/272/Inst/MH/2013/RR-19]	Dr Ashish Bavdekar
4	Bharati Vidyapeeth (Deemed to be University) Medical College Hospital and Research Centre, Pune-Satara Road, Dhankawadi, Pune-411043,	Institutional Ethics Committee, Bharati Vidyapeeth (Deemed to be University) Medical College and Hospital, Institutional Ethics Committee Office 4th floor, Bharati Hospital & Research Centre Pune-Satara Road, Dhankawadi, Pune-411043,	Dr Neeta Hanumante

	Maharashtra, India	Maharashtra, India. [ECR/313/Inst/MH/2013/RR-19]	

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

1. The Phase 1/2 clinical trial should be conducted as per approved protocol titled “A Seamless Phase 1/2, double blind, randomized, placebo-controlled study to evaluate the safety and immunogenicity of Dengusiil in Indian adults and children ≥ 2 years of age” [Protocol No. Dengusiil-02 Version No. 2.0 Dated 24.05.2023]”
2. The clinical trial report of Phase-I with DSMB recommendations should be submitted before initiation of Phase-II.
3. The firm is required to constitute a DSMB to review the safety data.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.
6. Firm is required to submit Ethics Committee approval for clinical trial.

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Date: 2023.06.24 [illegible]

RAJEEV SINGH RAGHUVANSHI

Place: New Delhi
Date:

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