File No: BIO/CT/22/000019
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 Licensing Authority hereby permits M/s Serum Institute of India Pvt. Ltd. (SIIPL), 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India. Tel: 020- 26602113, 26602378, FAX: 020-26993945, 26993921. E-Mail: michael.vernekar@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: TCV01 Version No. 1 Protocol Date 08-FEB-2022** in the below mentioned clinical trial sites.

CT No.: CT-15/2022

2. Details of new drug or investigational new drug and clinical trial sites [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.

4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Place: New Delhi
Date: 17.06.2022

VENUGOPAL G SOMANI

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(Dr. V. G. Somani)
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>Typhoid Conjugate Vaccine (Bivalent)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Solution for injection (Intramuscular)</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 mL Vaccine contains:
<table>
<tr><th>Ingredient</th><th>Quantity</th></tr>
<tr><td>Purified Vi polysaccharide from Salmonella Typhi conjugated to Tetanus Toxoid</td><td>25 µg</td></tr>
<tr><td>Purified O-Specific Polysaccharide from Salmonella Paratyphi A is conjugated to Diphtheria Toxoid</td><td>25 µg</td></tr>
<tr><td>Tris Buffer</td><td>0.30 mg</td></tr>
<tr><td>Mannitol</td><td>25 mg</td></tr>
<tr><td>2 Phenoxyethanol*</td><td>2.5 mg</td></tr>
<tr><td>Water for Injection</td><td>q.s.</td></tr>
</table>
* for multi dose presentation only</td></tr>
<tr><td>Indications:</td><td>for active immunization for prevention of Typhoid Fever and Paratyphoid A 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	Human Pharmacology Unit, Syngene International Limited, Clinical Development, Tower I, Semicon Park, Electronic City Phase II, Hosur Road, Bengaluru – 560 100, India	Sri Venkateshwara Hospital Ethics Committee, Sri Venkateshwara Hospitals, #27, 29th Main Road, Rashtra Kuvempu Nagara, BTM 2nd Stage, BTM Layout Bengaluru – 560076, Karnataka, India ECR/298/Inst/KA/2013/RR-19	Dr. Anil K

In addition to point 4, the permission is subject to following conditions:

i. The clinical trial shall be conducted as per protocol titled "A Double-Blind, Randomized, Active Controlled Phase I Clinical Study to assess the Safety and Tolerability of SII Typhoid Conjugate Vaccine (Bivalent) in Healthy Adults." Protocol Number: TCV: 01 Version and date: 1.0 dated 08 February 2022.

ii. DSMB shall be constituted for assessment of safety data of clinical trial.

iii. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.

iv. Firm is required to submit updated stability data (accelerated & real time) of Drug substances & Drug product and ensure its stability during clinical trial.

v. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL G SOMANI

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Date: 2022.06.17 15:50:46 +05'30'

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: 17.06.2022