File No: BIO/CT/22/000063
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: pks@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol Number: PCV-10-005 Protocol Version 1.1 Dated: 25 Aug 2022** in the below mentioned clinical trial sites.

CT No.: CT-23/2022

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.

Place: New Delhi
Date: 20.10.2022

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (10- Valent)
Therapeutic class:	Vaccine
Dosage form:	Suspension for injection for Intramuscular route of administration.
Composition:	Each dose of 0.5 mL Vaccine contains: Saccharide for serotypes 1,5, 9V, 14, 19A, 19F, 23F, 7F, 6A — 2 µg Saccharide for serotype 6B — 4 µg Conjugated to CRM197 carrier protein — 19 to 48 µg Aluminium (as Aluminium phosphate) — 0.125 mg L-Histidine — 1.55 mg Succinic acid — 1.18 mg Sodium Chloride — 4.50 mg Polysorbate-20 — 0.05 mg Thiomersal* — 0.005% Water for Injection — q.s. to 0.5 ml * for multi dose presentation only
Indications:	For active immunization against invasive disease & pneumonia caused by *Streptococcus pneumonia* serotypes 1,5, 9V, 14, 19A, 19F, 23F, 7F, 6A & 6B in infants from 6 weeks of age group for 3 dose regimen (dosing schedule : 6, 10 & 14 weeks)

Details of clinical trial sites-

S.No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KEM Hospital Research Centre, Vadu Rural Health Program, A/P-Vadu Budruk, Taluka- Shirur, District Pune - 412216, Maharashtra	KEM Hospital Research Centre Ethics Committee, Sardar Moodliar Road, Rasta Peth Pune 411011, Maharashtra, India ECR/272/Inst/MH/2013/RR-22	Dr. Ashish Ramesh Bavdekar

In addition to point 3, the permission is subject to following conditions:

i. The clinical trial shall be conducted as per protocol titled "A Phase 4, Cross-Sectional Study to Evaluate the Pneumococcal Nasopharyngeal Carriage in Healthy Toddlers Following Vaccination with 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) as Part of Universal Immunization Program in India As Compared To Non-vaccinated Toddlers" Protocol Number: PCV-10-005 Protocol Version 1.1 Dated: 25 Aug 2022.
ii. The permission is subject to approval of 10-Valent Pneumococcal conjugate vaccine for administration in 2+1 dose schedule (6 weeks, 14 weeks & 9 months).
iii. The firm is required to vaccinate the unvaccinated subject participants with the approved Pneumococcal vaccine after collection of swab sample.

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

Place: New Delhi
Date: 20.10.2022