File No: BIO/CT/25/000043
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

From:

The Drugs Controller General, India
Directorate General of Health Services,

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

To

M/s Serum Institute of India Pvt. Ltd,
212/2, Hadapsar, Pune, Off. Soli Poonawalla Road.
Maharashtra (India) - 411028.

Subject: Permission for conducting a clinical trial titled "A Phase 1, Prospective, Randomized, Two-Arm, Active-Controlled, and Double-Blind Study to Evaluate the Safety, Tolerability and Immunogenicity of Serum Institute of India's 21-valent Pneumococcal Conjugate Vaccine (SIIPCV21) in Healthy Indian Adults". [Protocol No. PCV-21-001, Version 1.0, dated: 06th March 2025]"- regarding.

Reference: Your Application No. BIO/CT04/FF/2025/48498 dated 25-MAR-2025 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2025/48498 dated 25-MAR-2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (21 Valent)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH RAGHUVANSHI
Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.09.08 10:22:40 +05'30'

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

File No: BIO/CT/25/000043
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, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) – 411028, Telephone No.: 91-20-26993900, FAX: 91-20-26993921 to conduct clinical trial of the new drug or investigational new drug as per protocol number: PCV-21-001, Version 1.0, dated: 06th March 2025 in the below mentioned clinical trial sites.

CT No.: CT-14/2025

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

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.09.08 10:23:59 +05'30'

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

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (21- Valent)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Suspension for Injection</td></tr>
<tr><td>Composition:</td><td>Composition:

Each dose of 0.5 ml after reconstitution contains:

<table>
<tr><th>Name of the Ingredients</th><th>Quantity per Dose (0.5 mL)</th><th>Reference to Quality Standard</th><th>Function/s</th></tr>
<tr><td colspan="4">Purified Pneumococcal Bulk Conjugates (Active Drug Substance)</td></tr>
<tr><td>Saccharide from serotypes 1, 2, 5, 7F, 8, 10A, 11A, 12F,14,18C,19F, 23F and 33F conjugated to CRM197 carrier Protein</td><td rowspan="3">2.0 µg</td><td rowspan="3">BP/WHO/IH</td><td rowspan="4">Pneumococcal antigens</td></tr>
<tr><td>Saccharide from serotypes 6A, 9V,15B, 19A, 22F conjugated to Tetanus toxoid carrier protein</td></tr>
<tr><td>Saccharide from serotypes 4 and 24F conjugated to Diphtheria Toxoid carrier Protein</td></tr>
<tr><td>Saccharide from serotype 6B conjugated to CRM197 carrier protein</td><td>4.0 µg</td><td>BP/WHO/IH</td></tr>
<tr><td colspan="4">Inactive Ingredients (Excipients)</td></tr>
<tr><td>Aluminium (as Aluminium Phosphate)</td><td>187.5 µg Al^{+++}</td><td>IH</td><td>Adjuvant</td></tr>
<tr><td>L-Histidine</td><td>1.55 mg</td><td>BP/Ph. Eur.</td><td>Stabilizer</td></tr>
<tr><td>Succinic acid</td><td>1.18 mg</td><td>IH</td><td>Buffering agent</td></tr>
<tr><td>Sodium Chloride</td><td>4.5 mg</td><td>IP/BP/Ph.Eur.</td><td>Tonicity modifier</td></tr>
<tr><td>Polysorbate-20</td><td>100.0 µg</td><td>IP/BP/Ph.Eur.</td><td>Surfactant</td></tr>
<tr><td>2- Phenoxyethanol **</td><td>0.8%</td><td>IP/BP/Ph.Eur.</td><td>Preservative</td></tr>
<tr><td>WFI</td><td>Quantity Sufficient</td><td>IP/BP/Ph.Eur./ USP</td><td>Solvent/Base</td></tr>
</table>

**: Used only in multidose formulation</td></tr>
<tr><td>Presentation:</td><td>Multidose (5 dose vial)</td></tr>
<tr><td>Indication(s):</td><td>For active immunization for prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae.</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	Seth GS Medical College & KEM Hospital ,Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Acharya Donde Marg, Parel, Mumbai 400012, Maharashtra, India	Institutional Ethics Committee (IEC)-I Seth GS Medical College and KEM Hospital, UG/PG Hostel Building, Ground Floor, KEM Hospital Campus, Dr. S. S. Rao Road, Parel, Mumbai 400012, Maharashtra, India. EC Registration no: ECR/229/Inst/MH/2013/RR-24	Dr. Nithya Gogtay
2	KEM Hospital Research Centre, Department of Medicine, KEM Hospital Research Centre, TDH Building 3rd Floor, Sardar Moodliar Road, Rasta Peth, Pune 411011, Maharashtra, India	KEM Hospital Research Centre Ethics Committee KEM Hospital Research Centre Building,3rd Floor, Room No-303, Sardar Moodliar Road, Rasta Peth Pune 411011, Maharashtra, India EC Registration no: ECR/272/Inst/MH/2013/RR-22	Dr. Pradeep D'Costa
3	Postgraduate Institute of Medical Education and Research, Clinical Pharmacology Unit under Department of Pharmacology, and Department of Community Medicine and School of Public Health, Postgraduate Institute of Medical Education and Research, Sector - 12, Chandigarh -160012, India	Institute's Ethics Committee, Postgraduate Institute of Medical Education and Research, Room No.6006, IEC Office 6th Floor, PN Chuttani Block, Chandigarh-160012, India EC Registration no: ECR/25/Inst/CH/2013/RR-20	Dr. Madhu Gupta

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

1. The Phase-I clinical trial should be conducted as per approved protocol titled "A Phase 1, Prospective, Randomized, Two-Arm, Active-Controlled, and Double-Blind Study to Evaluate the Safety, Tolerability and Immunogenicity of Serum Institute of India's 21-valent Pneumococcal Conjugate Vaccine (SIIPCV21) in Healthy Indian Adults". [Protocol No. PCV-21-001, Version 1.0, dated: 06th March 2025].
2. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
3. The firm shall use CDL, Kasauli certified batches in the Phase I clinical trial.
4. The firm shall submit Ethics Committee approval for proposed Phase-I clinical trial.

5. The firm shall ascertain that the available long term stability data shall cover the duration of clinical trial.
6. The firm shall submit the on-going stability studies data of the applied product i.e., Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (21-Valent).
7. The firm is required to constitute a DSMB to review the safety data.

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
Date: 2025.09.08 10:24:30 +05'30'

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

Place: New Delhi
Date: