File No: BIO/CT/24/000070
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.: 912026602451, FAX: 912026993921 to conduct Phase-III clinical trial of the new drug or investigational new drug as per Protocol number: ACYWX-05, Version: 1.0 Dated 16-MAY-2024 in the below mentioned clinical trial sites.

CT No.: CT- 12/2024

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

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(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>Meningococcal(A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Freeze-dried formulated vaccine (5-dose vial and single-dose vial)</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 ml after reconstitution contains :</td></tr>
<tr><td></td><td>
<table>
<tr><th rowspan="2">Name of Ingredients</th><th colspan="2">Quantity per dose (0.5 ml) after reconstitution</th></tr>
<tr><th>1-Dose Presentation</th><th>5-Dose Presentation</th></tr>
<tr><td>N. meningitidis group A polysaccharide[1]</td><td>5 µg</td><td>5 µg</td></tr>
<tr><td>N. meningitidis group C polysaccharide[2]</td><td>5 µg</td><td>5 µg</td></tr>
<tr><td>N. meningitidis group Y polysaccharide[2]</td><td>5 µg</td><td>5 µg</td></tr>
<tr><td>N. meningitidis group W polysaccharide[2]</td><td>5 µg</td><td>5 µg</td></tr>
<tr><td>N. meningitidis group X polysaccharide[1]</td><td>5 µg</td><td>5 µg</td></tr>
<tr><td>Purified Tetanus toxoid</td><td>7.8 to 33.4 µg</td><td>7.8 to 33.4 µg</td></tr>
<tr><td>Recombinant CRM197</td><td>11.7 to 50.1 µg</td><td>11.7 to 50.1 µg</td></tr>
<tr><td colspan="3">Excipients</td></tr>
<tr><td>Sucrose</td><td>11.90 mg</td><td>2.42 mg</td></tr>
<tr><td>Sodium citrate dihydrate</td><td>1.98 mg</td><td>0.40 mg</td></tr>
<tr><td>Tris buffer</td><td>0.48 mg</td><td>0.098 mg</td></tr>
<tr><td>Water for injection</td><td>q.s.</td><td>q.s.</td></tr>
</table>
[1] Conjugated to Purified Tetanus Toxoid
[2] Conjugated to Recombinant CRM197
</td></tr>
<tr><td>Indication(s):</td><td>Active immunization of individuals aged 9 months to 17 years against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, W and X.</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	Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab- 141008	Institutional Ethics Committee 2nd floor, Nr. Ward no.15, room no- 3201 Christian Medical College & Hospital, Brown Road, Ludhiana, Punjab-141008 [ECR/120/Inst/PB/2013/RR-19]	Dr. Ruby Singh
2	KEM Hospital Research Centre, Vadu Rural Health Program, Vadu Budruk, Taluka- Shirur, District- Pune	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth,	Dr. Anand Kawade

	412216	Pune-411011, Maharashtra. [ECR/272/Inst/MH/2013/RR-22]	
3	JSS Hospital, Mysuru- 570004, Karnataka	Institutional Ethics Committee, JSS Medical College JSS Hospital, Mysore JSS Medical College, Sri Shivarathreeshwara Nagara, Mysuru (Mysore), Karnataka-570015. [ECR/387/Inst/KA/2013/RR-22]	Dr. Deepti Thandaveshwara
4	Preventive and Therapeutic Clinical Trial Unit (PTCTU), 2nd Floor, Department of Community Medicine, SUM Annex Building, IMS and SUM Hospital, K-8, Kalinga Nagar, Bhubaneswar, Odisha District – Khordha, PIN – 751003.	IEC IMS and SUM Hospital, IMS and SUM Hospital, K8 Kalinganagar, Shampur, Bhubaneswar, Khordha, Orissa-751003, India. [ECR/627/Inst/OR/2014/RR-20]	Dr. Sandeep Kumar Panigrahi
5	Dr. D.Y. Patil Medical College, Hospital and Research Centre, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra 411018.	Ethics Committee, Dr. D. Y. Patil Vidyapeeth, Sant Tukaram Nagar, Pimpri, Pune 411018 [ECR/361/Inst/MH/2013/RR-24]	Dr. Shailaja Mane
6	Institute of Child Health 11, Dr. Biresh Guha Street, Kolkata, West Bengal - 700001.	Institutional Ethics Committee ICH Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata, West Bengal - 700001, India. [ECR/359/Inst/WB/2013/RR-24]	Dr. Kheya Ghosh Uttam

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

I. The clinical trial should be conducted as per approved protocol titled “A Phase 3, Randomized, Double-blind, Controlled, Multi-Center Study to Compare Immunogenicity and Safety of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Indian Children of 9 months to 17 Years of Age” vide Protocol no. ACYWX-05, Version No. 1.0 Dated 16-MAY-2024.

II. The firm is required to constitute a DSMB to review the safety data.

III. Firm is required to submit Ethics Committee approval for Phase-III clinical trial.

IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.

V. Only CDL, Kasauli certified batches shall be used in the Phase-III clinical trial in India.

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