File No: BIO/CT/24/000140
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 permit M/s. Biological E. Limited, Plot No. 1, Biotech Park, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India -500 078 India Tel: 91-40-67388000 Fax: 91-40-30128159 to conduct clinical trial of the new drug or investigational new drug as per Protocol number: BECT091/MCV-Phase-I/CTP-01 Version No. 1.0, Dated: 13.09.24 in the below mentioned clinical trial sites.

CT No.: CT- 19/2025

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

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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 Group A, C, W-135, Y, X Conjugate Vaccine (Adsorbed & Unadsorbed)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccines (Bacterial Vaccines)</td></tr>
<tr><td>Dosage form:</td><td>Solution for Intramuscular injection</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 ml contains:
<table>
<tr><th>Ingredients</th><th>Quantity</th></tr>
<tr><td>Neisseria meningitidis group A Polysaccharide conjugated to TT#</td><td>5 µg</td></tr>
<tr><td>Neisseria meningitidis group C Polysaccharide conjugated to TT#</td><td>5 µg</td></tr>
<tr><td>Neisseria meningitidis group Y Polysaccharide conjugated to CRM_{197}#</td><td>5 µg</td></tr>
<tr><td>Neisseria meningitidis group W-135 Polysaccharide conjugated to TT#</td><td>5 µg</td></tr>
<tr><td>Neisseria meningitidis group X Polysaccharide conjugated to TT#</td><td>5 µg</td></tr>
<tr><td>Total Carrier Protein content (#conjugated protein moiety)</td><td>16-100 µg</td></tr>
<tr><td>Aluminium Phosphate (Expressed as Al^{3+})*</td><td>NMT 1.25 mg</td></tr>
<tr><td>Thiomersal (preservative)</td><td>25 µg</td></tr>
<tr><td>Polysorbate 20 (stabilizer)</td><td>NMT 250 ppm</td></tr>
<tr><td>40 mM Sodium chloride*</td><td>q.s to 0.5 mL</td></tr>
<tr><td>Phosphate buffer saline</td><td>q.s to 0.5 mL</td></tr>
<tr><td colspan="2">* Applicable for Adsorbed formulation only.</td></tr>
</table></td></tr>
<tr><td>Presentation:</td><td>2.5 mL (5 dose)</td></tr>
<tr><td>Indication(s):</td><td>Meningococcal Group A, C, W-135, Y, X Conjugate Vaccine is indicated for active immunization for the prevention of invasive meningococcal disease caused by N. meningitidis serogroups A, C, W-135, Y, 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.	Guru Teg Bahadur (GTB) Hospital, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi - 110095, India.	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur HospitalGuru Teg Bahadur Hospital Dilshad Garden Delhi EastDelhi Delhi - 110095 India **[ECR/510/Inst/DL/2014/RR-20]**	Dr. Shiva Narang M.B.B.S. & MD (General Medicine)
2.	St. Theresa's Hospital (STH), Erragadda Main Road, Czech Colony, Sanath Nagar, Hyderabad – 500038, Telangana, India.	Ethics Committee, St. Theresa's Hospital, Sanath Nagar, Opp. Erragadda Raitu Bazar, Hyderabad – 500038, Telangana, India. **[ECR/230/INST/AP/2013/RR-22]**	Dr. A. Venkateshwar Rao M.B.B.S & DNB (General Medicine)

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 Prospective, Open label, randomized, controlled Phase-I clinical study to evaluate the safety and immunogenicity of single intramuscular dose of Biological E’s Meningococcal Conjugate Vaccine, administered to 18-45 years-old healthy adults (Protocol number: BECT091/MCV-Phase-I/CTP-01 Version No. 1.0, Dated: 13.09.24)”.
2. To submit updated stability data of three consistency batches.
3. A data safety monitoring board (DSMB) will be constituted to review the safety data for all the enrolled subjects in the study.
4. Firm shall submit Ethics Committee approval for proposed Phase-I clinical trial.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.
6. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
7. To submit bioanalytical method validation report.

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