File No: BIO/CT/22/000101
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 Biological E -Shameerpet, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village Shameerpet Mandal (India) - 500078 to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: BECT077/IPV-S19-Phase-II/CTP-01, Version no.:1.1 Final, dated 26-Dec-2022 in the below mentioned clinical trial sites.

CT No.: CT- 06/2023

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.

Place: New Delhi
Date:

RAJEEV SINGH RAGHUVANSHI

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(Dr. Rajeev Singh Raghuvanshi)
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 colspan="2">Inactivated Poliomyelitis Vaccine (Adsorbed)</td></tr>
<tr><td>Therapeutic class:</td><td colspan="2">Vaccine</td></tr>
<tr><td>Dosage form:</td><td colspan="2">Intramuscular injection</td></tr>
<tr><td rowspan="10">Composition:</td><td colspan="2">Each dose of 0.5 ml contains</td></tr>
<tr><td>Name of Active ingredient</td><td>Quantity</td></tr>
<tr><td>Type -1(S19/MahP1/N18S)#</td><td>20 D Antigen Unit</td></tr>
<tr><td>Type-2(S19/MEF2P1/N18S)#</td><td>4 D Antigen Unit</td></tr>
<tr><td>Type -3(S19/SktP1/N18S)#</td><td>16 D Antigen Unit</td></tr>
<tr><td>Name of Active ingredient</td><td>Quantity</td></tr>
<tr><td>Aluminium Hydroxide gel (equivalent to Al+++</td><td>≤ 1.25 mg</td></tr>
<tr><td>2-Phenoxyethanol</td><td>4.0 mg</td></tr>
<tr><td colspan="2">#Produced in Vero cells</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td>Indication(s):</td><td colspan="2">For active immunization against Poliomyelitis Types 1, 2 and 3.</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	Cheluvamba Hospital, Mysore medical college and Research institution, Irwin road, Mysore-570001	Cheluvamba Hospital, Irwin Rd, Devraj Mohalla, Mysuru 570001, Karnataka, India [ECR/134/Inst/KA/2013/RR-19]	Dr. Prashanth S.
2	GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India.	GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India [ECR/510/Inst/DL/2014/RR-20]	Dr. Manish Narang
3	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre J N Medical College, Nehru Nagar, Belagavi –590010, Karnataka, India	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre J N Medical College, Nehru Nagar, Belagavi – 590010,Karnataka, India [ECR/211/Inst/KA/2013/RR-19]	Dr N S Mahantshetti

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 prospective multicentre open label randomized active controlled Phase-II study to evaluate safety, tolerability and immunogenicity of inactivated poliomyelitis vaccine (Adsorbed) of Biological E Limited in 6-8 weeks old infants”[Protocol no. BECT077/IPV-S19-Phase-II/CTP-01, Version no.:1.1 Final, dated 26-Dec-2022].
II. The firm is required to constitute a DSMB to review the safety data.
III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability program.
IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date:

RAJEEV SINGH RAGHUVANSHI

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