

File No: BIO/CT/22/000092
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 Mr. Varma B S S S Bhupathiraju of 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.: BECT071/JEV-PIII_LE/CTP-01, Version no.:2.0 dated 27.12.2022 in the below mentioned clinical trial sites.

CT No.: CT- 04/2023

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: 23-05-2023

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

Annexure: Details of New Drug or Investigational New Drug:

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| Name of the new drug or investigational new drug: | Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) | | |
| Therapeutic class: | Vaccine | | |
| Dosage form: | Suspension for Intramuscular Injection | | |
| Composition: | Each dose of 0.5 ml contains | | |
| | Composition | Quantity | |
| | | 6mcg/0.5ml for Adult subjects 49-70 years | 3mcg/0.5ml for infants 9-12 months |
| | Purified inactivated Japanese encephalitis Virus Vaccine Strain (SA 14-14-2) ¹ | 6 µg | 3 µg |
| | Aluminium as Aluminium Hydroxide | 0.1% w/v | 0.1% w/v |
| | Thiomersal BP* | 0.005% w/v | 0.005% w/v |
| Phosphate Buffer Saline | q.s | q.s | |
| | ¹ Produced in Vero cells *Thiomersal-in Multi dose vials | | |
| Indication(s): | 3mcg/0.5ml for infants 9-12 months: For active immunization to prevent Japanese Encephalitis virus in infants aged 9-12 months. 6mcg/0.5ml for Adult subjects 49-70 years: For active immunization to prevent Japanese Encephalitis virus in adults aged 49-70 years. | | |

Details of clinical trial sites-

| S. No. | Name and Address of Clinical Trial Site | Ethics Committee details | Name of Principal Investigator |
|--------|--|--|---|
| 1. | Cheluvamba Hospital, Irwin Rd, Devraj Mohalla, Mysuru 570001, Karnataka , India | IEC- Mysore Medical College and Research Institute Irwin Road Mysuru Mysuru (Mysore) Karnataka - 570001 (ECR/134/Inst/KA/2013/RR-19) | Dr. Pradeep. N M.B.B.S, M.D(Paediatrics) |
| 2. | GTB Hospital, Delhi, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India | IEC –GTB Hospital, Delhi, (ECR/1117/Inst/DL/2018/RR-21) | Dr.Manish Narang M.B.B.S, M.D(Paediatrics) |
| 3. | KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, J N Medical College, Nehru Nagar, Belagavi – 590010,Karnataka, India | IEC- KLE Academy of Higher Education & Research, JNMC Campus, Nehru Nagar, Belagavi, Karnataka – 590010 (ECR/211/Inst/KA/2013/RR-19) | Dr N S Mahantshetti M.B.B.S, M.D(Paediatrics) |
| 4. | JLN Medical College , Kala Bagh, Ajmer 305001, Rajasthan 305001 | IEC- Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan – 305001 (ECR/1156/Inst/RJ/2018/RR-22) | Dr. Jai Prakash Narayan M.B.B.S, M.D(Paediatrics) |

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| 5. | Grant Medical College & Sir J.J Hospital, J J Marg, Nagpada, Mumbai Central, Mumbai 400008, Maharashtra, India | IEC-Grant Government Medical College, JJ Road, JJ Hospital Compound, Mumbai Central, Mumbai, Mumbai City, Maharashtra – 400008 (ECR/382/Inst/MH/2013/RR-19) | Dr.Gupta Hemant Ramsharan M.B.B.S, M.D (General Medicine) |
| 6. | Inclen Trust - Nazareth Hospital, Arbuthnot Rd, near Police Point, Laitumkrah, Shillong - 793003, Meghalaya, India | IEC- The INCLEN Trust International SOMAARTH DDESS, Mawngap Rim, Mawphlang East, Khasi Hills, Meghalaya – 793121 (ECR/361/Inst/ML/2022) | Dr.Abhishek Agarwal M.B.B.S, M.D (Community Medicine) |
| 7. | ESIC Medical College & Hospital, New Industrial Town, Faridabad-121001, Haryana, India | IEC-ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana – 121001 (ECR/1539/Inst/HR/2021) | Dr.Anil Kumar Pandey M.B.B.S, M.D (Physiology) |
| 8. | King George Hospital, Maharani Peta, Visakhapatnam 530002 Andhra Pradesh, India | IEC- King George Hospital, MaharaniPeta, Visakhapatnam, Andhra Pradesh - 530002 (ECR/197/Inst/KGH/2013/RR-19) | Dr. S. Narayana Rao M.B.B.S, M.D (Paediatrics) |

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 III, open label, prospective, multicenter, label expansion study to evaluate safety and immunogenicity of Inactivated Japanese Encephalitis Vaccine (JEEV™) in 49-70 years old adults and in the healthy 9-12 months old infants either alone or when co-administered with a licensed MMR vaccine at 9 months of age” [Protocol no. BECT071/JEV-PIII_LE/CTP-01, Version no.:2.0 dated 27.12.2022].
- 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.
- IV. Firm is required to submit copy of Insurance Certificate of subject trial.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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

Place: New Delhi
Date: 23-May-2023