File No: BIO/CT/23/000127
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, Phase II, Kolthur Village Shameerpet, Medchal-Malkajgiri District, Telangana-500078, India to conduct Phase-II clinical trial of the new drug or investigational new drug as per [Protocol no. BECT084/LHV-P-II/CTP-01, Version no. 1.0 dated 15.09.2023] in the below mentioned clinical trial sites.

CT No.: CT- 01/2024

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:

Name of the new drug or investigational new drug:	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Inactivated Poliomyelitis and *Haemophilus influenzae* Type b Conjugate Vaccine (Adsorbed)		
Therapeutic class:	Vaccine		
Dosage form:	Suspension for Intramuscular injection		
Composition:	Each dose of 0.5 mL contains		
	Name of Ingredients	**Quantity**	
		Hexavalent vaccine with half dose strength of IPV	**Hexavalent vaccine with full dose strength of IPV**
	Diphtheria Toxoid	≥ 30 IU (≥20Lf to ≤ 30Lf)	≥ 30 IU (≥20Lf to ≤ 30Lf)
	Tetanus Toxoid	≥ 60 IU (≥5Lf to ≤ 25 Lf)	≥ 60 IU (≥5Lf to ≤ 25 Lf)
	B. Pertussis (Whole cell, Killed)	≥ 4 IU	≥ 4 IU
	r-HBsAg (Recombinant HBs Antigen produced in *Pichia pastoris)*	12.5 µg	12.5 µg
	Inactivated poliomyelitis virus Type -1 (S19/MahP1/N18S)# Type-2 (S19/MEF2P1/N18S)# Type-3 (S19/SktP1/N18S)#	20 D Antigen Units 4 D Antigen Units 16 D Antigen Units	40 D Antigen Units 8 D Antigen Units 32D Antigen Units
	Purified Capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7 µg of Tetanus Toxoid	11 µg	11 µg
	Al^{+++} (As $AlPO_4$)	≤ 1.25 mg	≤ 1.25 mg
	2-Phenoxyethanol	4.0 mg	4.0 mg
	# Produced in Vero cells. Poliomyelitis vaccine bulks (Types 1, 2 and 3) were inactivated using formaldehyde.		
Indication(s):	For active immunization to prevent Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis type 1, 2, and 3 and *Haemophilus influenzae* type b.		

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Sites	Ethics Committee details	Name of Principal Investigators
1	Clinical Trial Unit, MRU (Multidisciplinary Research Unit), Basement, ESIC Medical College and Hospital, NH-3, NIT, Faridabad, Haryana 121001, India.	Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College and Hospital, NH-3, NIT, Behind BK Hospital, Faridabad, Haryana – 121001, India. [ECR/1539/Inst/HR/2021]	Dr. Anil Kumar Pandey
2	Sharawathi Ward Opposite Psychiatric ward, KLEs Dr Prabhakar Kore Hospital & Medical Research Centre,	Institutional Ethics Committee, KLE University, KLE Dr. PK Hospital and MRC, Nehru Nagar Belagavi (Belgaum), Karnataka –	Dr. N. S. Mahantshetti

	Nehru Nagar, Belagavi – 590010,Karnataka, India	590010,India [ECR/211/Inst/KA/2013/RR-19]	
3	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan, India. [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Jai Prakash Narayan
4	Department of Pediatrics, King George Hospital, Collectorate junction, Maharanipeta, Visakhapatnam - 530002, Andhra Pradesh, India.	Institutional Ethics Committee, King George hospital, Maharanipeta, Collector Office Junction, Visakhapatnam, Andhra Pradesh-530002, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. B. S. Chakravarthy
5	Shubham Sudbhawana Super Specialty Hospital, B31/80, 23B - Bhogabeer, Lanka, Varanasi-221005, Uttar Pradesh	Ethics Committee Shubham Sudbhawana Superspeciality Hospital, B31/80, 23B - Bhogabeer, Lanka, Varanasi, 221005, Uttar Pradesh, India. [ECR/667/Inst/UP/2014/RR-20]	Dr. Madhukar Pandey

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 randomised active controlled Phase-II safety and immunogenicity study with 3-doses of Biological E’s Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old infants” [Protocol no. BECT084/LHV-P-II/CTP-01, Version no. 1.0 dated 15.09.2023]
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-II 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 clinical trial.

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