File No: BIO/CT/22/000107
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.: BECT078/LHV-PI/CTP-02, Version no.:2.0 dated 28.12.2022 in the below mentioned clinical trial sites.

CT No.: CT- 03/2023

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.

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

Place: New Delhi
Date: 27-04-2023

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	DTwP-HepB-IPV-Hib Vaccine (Liquid Hexavalent Vaccine)		
Therapeutic class:	Vaccine		
Dosage form:	Intramuscular injection		
Composition:	Each dose of 0.5 ml contains		
	Name of Active ingredient	**Quantity**	
		Half strength of S19 IPV	**Full strength of S19 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 HBsAntigen 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 8D Antigen Units 32D Antigen Units
	Purified Capsular Polysaccharide of Hib (PRP)covalently linked to 20 to 36.7µg of Tetanus Toxoid	11 µg	11 µg
	Name of Active ingredient	**Quantity**	
	Al+++(As AlPO4)	≤ 1.25 mg	≤ 1.25 mg
	2-Phenoxyethanol	4.0 mg	4.0 mg
	# Produced in Vero cells. Poliomyelitis vaccine bulks (Types 1,2and 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 Site	Ethics Committee details	Name of Principal Investigator
1	GTB Hospital attached to UCMS, Tahirpur Rd, GTB Enclave, Dilshad Garden, Delhi 110095, India	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden Delhi East Delhi Delhi - 110095 India [ECR/510/Inst/DL/2014/RR-20]	Dr. Manish Narang,
2	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre J N Medical College, Nehru Nagar, Belagavi – 590010,Karnataka, India	Institutional Ethics Committee, KLE University, KLE University KLE Dr.PK Hospital and MRC Nehru Nagar Belagavi Belagavi Belagavi (Belgaum) Karnataka - 590010 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 Randomised Phase-I study to evaluate the Safety, Reactogenicity & Immunogenicity of single booster dose of Biological E’s Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 16-24 months old healthy toddlers” [Protocol no. BECT078/LHV-PI/CTP-02, Version no.:2.0 dated 28.12.2022].
II. The firm is required to constitute a DSMB to review the safety data.
III. Firm is required to obtain manufacturing permission in Form CT-11 for clinical trial purpose before initiation of clinical trial.
IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
V. Firm is required to submit copy of Insurance Certificate of subject trial.
VI. 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: 27-April-2023