File No: BIO/CT/24/000001

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 grant permission to M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana–500078, India; Telephone No.: 91-40-67388000, FAX: 91-40-30128159, E-mail: info@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per Protocol no. BECT085/PCV-Phase-II/CTP-02, Version No.: 2.0 dated 02.04.24, Amendment No.: 1.0 dated 02.04.24 to conduct Phase-II clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT-11 /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.
4. It may kindly be noted that merely granting permission to conduct clinical trials with the vaccine does not convey or imply that based on the clinical trial data generated with the vaccine, permission to market this vaccine in the country with automatically be granted to you.

RAJEEV SINGH RAGHUVANSHI

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

Date:
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24 Valent)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular injection	
Composition:	**Each dose of 0.5 mL Vaccine contains:**	
	Active ingredients	**Quantity**
	Pneumococcal polysaccharide serotype 1	3.0 µg*
	Pneumococcal polysaccharide serotypes 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F, 6A, 8, 10A, 11A, 12F, 15A, 23A, 23B, 24F and 35B	2.2 µg*
	Pneumococcal polysaccharide serotype 6B	4.4 µg*
	Inactive ingredient	
	Adsorbed onto Aluminum Phosphate, as Al^{+++}	≤ 0.75 mg#
	*The concentration represents the polysaccharide concentration. # Aluminum (Al^{+++}) is added at a concentration of 0.5mg / 0.5 mL. Serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F conjugated to 20-50 µg of CRM_{197}. Serotypes 6A, 8, 10A, 11A, 12F, 15A, 23A, 23B, 24F, 35B conjugated to 15-34 µg of PsaA.	
Indication	Active immunization for the prevention of disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15A, 18C, 19A, 19F, 22F, 23A, 23B, 23F, 24F, 33F & 35B.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Sites	Ethics Committee details	Name of Principal Investigators
1	King George Hospital Collectorate Junction, Maharanipeta, Visakhapatnam –530002, Andhra Pradesh.	Institutional Ethics Committee King George Hospital Visakhapatnam, Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. B.S. Chakravarthy
2	KLEs Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka.	Institutional Ethics Committee KLEs Prabhakar Kore Hospital & Medical Research Centre, Belagavi, Karnataka, India. [ECR/211/Inst/KA/2013/RR-24]	Dr. N.S. Mahantshetti,

3	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer 305001, Rajasthan.	Institutional Ethics Committee Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan, India. [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Jai Prakash Narayan
4	ESIC Medical College & Hospital, New Industrial Town, Faridabad - 121001, Haryana	Institutional Ethics Committee ESIC Medical College and Hospital, Faridabad, Haryana, India. [ECR/1539/Inst/HR/2021]	Dr. Anil Kumar Pandey

In addition to point 4, the permission is subject to following condition(s):

I. The clinical trial should be conducted as per approved protocol titled “An open label randomised Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E’s 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14 weeks dosing schedule” [Protocol no. BECT085/PCV-Phase-II/CTP-02, Version No.: 2.0 dated 02.04.24, Amendment No.: 1.0 dated 02.04.24]

II. Firm is required to obtain Form CT-11 to manufacture Pneumococcal polysaccharide conjugate vaccine (Adsorbed) (24 Valent) for further clinical trial purpose.

III. Only CDL, Kasauli certified batches shall be used in Phase-II clinical trial.

IV. To submit Ethics Committee approval for Phase-II clinical trial.

V. To submit Insurance Certificate for proposed Phase-II Clinical trial.

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

Date:
Place: New Delhi