

File No: BIO/CT/21/000135
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 Telephone No.: null FAX: null E-Mail: VARMA.BHUPATHIRAJU@BIOLOGICALE.COM to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: BECT075/PCV-Ph-I/01 Version No. 1.0, Dated 01-SEP-2021 in the below mentioned clinical trial sites.

CT No.: CT- 07/2022

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: 25-MAR-2022

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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

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 contains	
	Name of Active ingredient	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 & 35B	2.2 µg
	Pneumococcal Polysaccharide Serotype 6B	4.4 µg
	Name of Active ingredient	Quantity
	Adsorbed onto Aluminum Phosphate, as Al ⁺⁺⁺	≤ 0.75 mg
	Succinic Acid	295 µg
	Polysorbate 20	0.35 mg
	0.9% w/v Sodium Chloride Solution	q.s.
	1 N Sterile Hydrochloric Acid Solution	q.s.
	1 N Sterile Sodium Hydroxide Solution	q.s.
Indication(s):	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 and 35B.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	ESIC Medical College & Hospital, Room No. 440, 4th Floor, NH-3 behind BK Hospital New Industrial Town, Faridabad-121001, Haryana	Institutional Ethics Committee 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	Grant Govt Medical College & Sir JJ Hospital, JJ Marg, Nagpada, Mumbai Central, 400008, Maharashtra	Institutional Ethics Committee, Grant Govt Medical College, JJ Road, JJ Hospital compound Mumbai, Maharashtra -400008 India [ECR/382/Inst/MH/2013/RR-19]	Dr. Gupta Hemant Ramsharan

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 open label non-comparative Phase-I clinical study to evaluate safety, tolerability, reactogenicity and immunogenicity of single intramuscular dose of Biological E's 24valent pneumococcal polysaccharide conjugate vaccine in 18-45 years-old healthy adults" [Protocol no. BECT075/PCV-Phase-I/CTP-01, Version no.:1.0 Final dated 01.09.2021].
- 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.

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(Dr. V. G. Somani)

Drugs Controller General (India)
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Place: New Delhi
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