

**File No: BIO/CT/24/000082**

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, India –500078; Telephone No.: 91-40-67388000, FAX: 91-40-30128159, E-mail: [info@biologicale.com](mailto:info@biologicale.com) to conduct clinical trial of the new drug or investigational new drug as per Protocol no. BECT090/PCV14-Phase-IV/CTP-01 Version No.: 1.0 dated 17.06.24 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

**CT No.: CT-02/2025**

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.

Date:  
Place: New Delhi

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

**Annexure: Details of New Drug or Investigational New Drug:**

<b>Name of the new drug or investigational new drug:</b>	Pneumococcal polysaccharide conjugate vaccine (Adsorbed) (14-Valent)	
<b>Therapeutic class:</b>	Vaccine	
<b>Dosage form:</b>	Suspension for Intramuscular injection	
<b>Composition:</b>	<b>2.5 mL (5 dose) Presentation</b>	
	<b>Each dose of 0.5 mL Vaccine contains:</b>	
	<b>Active ingredients</b>	<b>Quantity</b>
	Pneumococcal polysaccharide serotype 1	3.0 µg
	Pneumococcal polysaccharide serotypes: 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, 33F. (each)	2.2 µg
	Pneumococcal polysaccharide serotype 6B	4.4 µg
	Adsorbed onto Aluminum Phosphate, as Al <sup>+++</sup>	≤ 0.75 mg
2-Phenoxyethanol	4 mg	
	Polysaccharides Conjugated to 20-50 µg of CRM <sub>197</sub> .	
<b>Indication:</b>	For active immunization against invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in children aged ≥ 5 years to < 18 years and adults aged ≥ 18 years and above.	

**Details of clinical trial sites-**

<b>S. No.</b>	<b>Name and Address of Clinical Trial Site</b>	<b>Ethics Committee details</b>	<b>Name of Principal Investigator</b>
1.	Aartham Multi Super Speciality Hospital, Department of Pediatrics, 1 <sup>st</sup> floor, Dr Vikram Sarabhai Marg, near Panjrapole Cross Road, L Colony, Ambawadi, Ahmedabad 380015, Gujarat, India.	Aartham Ethics Committee Aartham Hospitals LLP, Opp. Polytechnic, Near Panjarapole Cross Road, Ambawadi, Ahmedabad, Gujarat - 380015 [ECR/1520/Inst/GJ/2021]	Dr. Shreyans Shah MBBS, MD (Paediatrics)
2.	Belagavi Institute of Medical Sciences, Dr B R Ambedkar Rd, Sadashiv Nagar, 2 <sup>nd</sup> Floor, Belagavi -590019, Belgaum, Karnataka, India.	Institutional Ethics Committee, BIMS, Belagavi Institute Of Medical Sciences, Dr B R Ambedkar Road, Belagavi (Belgaum) Karnataka – 590001 [ECR/801/Inst/KA/2016/RR-20]	Dr. R. G. Viveki MBBS, MD (Community Medicine)
3.	Bharati Vidyapeeth (Deemed to be University) Medical College Hospital and Research Centre, Ground floor, Pune-Satara road, Dhankawadi, Pune-411043, Maharashtra, India.	Institutional Ethics Committee BVDU, Bharati Hospital and Research Centre, Bharati Hospital, Pune – Satara Road, Dhankawadi, Pune, Maharashtra 411043, India. [ECR/313/Inst/MH/2013/RR-24]	Dr. Sonali Hemant Palkar, MD, DCH (Community Medicine)

**File No: BIO/CT/24/000082**

4	Christian Medical College & Hospital, Brown Rd, 1st floor, CMC Campus, Ludhiana - 141008, Punjab, India.	Institutional Ethics Committee Christian Medical College & Hospital, Brown Rd, 1st floor, CMC Campus, Ludhiana -141008. [ECR/120/Inst/PB/2013/RR-24]	Dr. Avneet Singh MD (Community Medicine)
5	ESIC Medical College & Hospital, Room No. 440, 4 <sup>th</sup> Floor, NH-3 behind BK Hospital New Industrial Town, Faridabad-121001, Haryana, India.	Institutional Ethics Committee for ESIC Faridabad, ESIC Medical College And Hospital, NH-3 NIT Behind BK, Hospital, Faridabad, Haryana – 121001 [ECR/1539/Inst/HR/2021]	Dr. Onkar Singh Bhinder MBBS & MD (Paediatrics)
6	Gauhati Medical College & Hospital, Department of Medicine, 1st floor, OPD block, Narakasur Hilltop, Bhangagarh, Assam, Guwahati-781032, India.	Institutional Ethics Committee, GMCH, Gauhati Medical College And Hospital, 2nd Floor, Gauhati Medical College Main Building, Narakasur Hill Top, Guwahati, Kamrup, Metropolitan, Assam - 781032, India. [ECR/1470/Inst/AS/2020]	Dr. Anjan Jyoti Talukdar MBBS, MD (General Medicine)
7	GTB Hospital, Delhi, 6 <sup>th</sup> Floor, Tahirpur Rd, GTB Enclave, Dilshad Garden- 110095, North East, Delhi.	Guru Teg Bahadur Hospital Ethics Committee, Guru Teg Bahadur Hospital Dilshad Garden, Delhi East, Delhi – 110095. [ECR/510/Inst/DL/2014/RR-20]	Dr. Manish Narang MBBS & MD(Paediatrics)
8	JLN Medical College ,2nd Floor, Kala Bagh-305001, Ajmer, Rajasthan, India.	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan - 305001, India. [ECR/1156/Inst/RJ/2018/RR-22]	Dr. Jai Prakash Narayan MBBS & M.D (Paediatrics)
9	King George Hospital ,1 <sup>st</sup> Floor, Room no: 09, Dept of Paediatrics, Collectorate Junction, Maharanipeta, Visakhapatnam –530002, Andhra Pradesh.	Institutional Ethics Committee King George Hospital , Maharanipeta Collector Office Junction, Visakhapatnam, Andhra Pradesh, India. [ECR/197/Inst/KGH/2013/RR-20]	Dr. B.S. Chakravarthy, M.B.B.S & M.D (Paediatrics)
10	Panimalar Medical College Hospital & Research Institute, 3rd Floor, Varadharajapuram, Chennai Outer Ring Rd, Poonamallee, Chennai, 600123 Tamil Nadu, India.	PMCHRI-IHEC, Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Poonamallee, Chennai, Tiruvallur, Tamil Nadu. [ECR/1399/Inst/TN/2020]	Dr. Ramanath Andy Karayar MBBS, DCH, MD (Professor & HOD of Paediatrics)
11	PT. B D Sharma Post Graduate Institute of Medical Sciences & Hospital, 2 <sup>nd</sup> Floor, Rohtak - 124001, Haryana, India.	Institutional Ethics Committee, PGIMS UHS Rohtak, Pt. BD Sharma, Post Graduate Institute of Sciences, PGIMS UHS Rohtak- 124001, Haryana [ECR/293/Inst/HR/2013/RR-24]	Dr. Savita Verma MBBS & M.D (Pharmacology)

12	Sri Ramachandra Hospital, 1st floor, No. 1, Porur, Chennai - 600116, Tamil Nadu, India.	Institutional Ethics Committee SRIHER SRI RAMACHANDRA 1, Ramachandra Nagar, Porur, Chennai, Tiruvallur, Tamil Nadu - 600116 India [ECR/203/Inst/TN/2 013/RR-19]	Dr. P. Umapathy MBBS, MD (Paediatrics)
13	SSG General Hospital, 1 <sup>st</sup> floor, Anandpura, Vadodara 390001, Gujarat, India.	Institutional Ethics Committee for Human Research, Department of Pediatrics, Ward 17, First Floor, Medical College & SSG Hospital, Vadodara 390001, Gujarat, India. [ECR/85/Inst/GJ/2013/RR-24]	Dr. PareshKumar. A. Thakkar  MBBS, MD & DNB (Paediatrics)
14	St. Theresa's Hospital (STH), 1st Floor, Room No. 05, Erragadda Main Road, Czech Colony Sanath Nagar, Hyderabad 500038, Telangana, India.	Ethics committee, St Theresa's Hospital, Sanathnagar, Opp. Erragadda Raitu Bazar, Hyderabad, Telangana -500018, India. [ECR/230/Inst/AP/2013/RR-22]	Dr. G. Balakishor MBBS, DCH & DNB
15	BGS Global Institute of Medical Sciences, 2nd Floor, Dr. Vishnuvardhan Road, Kengeri-560060, Bangalore, Karnataka, India.	Institution Ethics committee, Department of community medicine, Room no: 01, Second floor, college building, BGS global Institute of medical sciences, 67 BGS Health and education city, Uttarahali road, Kengeri Bangalore south, Karnataka-560060 India. [EC/RENEW/INST/2024/17936]	Dr. Mohan M E MBBS, MD (General Medicine)

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 "A single blind, randomized, active-controlled, phase-IV study to evaluate immunogenicity and safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine (PNEUBEVAX-14), administered to healthy children aged 5 years to <18years and healthy adults aged 18 years and above" [Protocol no. BECT090/PCV14-Phase-IV/CTP-01 Version No.: 1.0 dated 17.06.24]
- II. Only CDL, Kasauli certified batches shall be used in Phase-II clinical trial.
- III. To submit study report of Reproduction and Developmental Toxicity studies in animals [DART] for Pneumococcal polysaccharide conjugate vaccine (Adsorbed) I.P. (14-Valent).
- IV. To submit Ethics Committee approval for proposed Phase-IV Clinical trial.

Date:  
Place: New Delhi

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

File No: BIO/CT/24/000082  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

FDA Bhawan Kotla Road,  
New Delhi-110002

**From:**

The Drugs Controller General, India  
Directorate General of Health Services,

**To,**

M/s Biological E. Limited, Plot No 1,  
Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri  
District, Telangana, India –500078

**Subject:** Permission for conducting clinical trial titled “ A single blind, randomized, active-controlled, phase-IV study to evaluate immunogenicity and safety of Biological E’s 14-valent pneumococcal polysaccharide conjugate vaccine (PNEUBEVAX-14), administered to healthy children aged 5 years to <18years and healthy adults aged 18 years and above” [Protocol no. BECT090/PCV14-Phase-IV/CTP-01 Version No.: 1.0 dated 17.06.24]”- regarding.

**Reference:** Your Application No. BIO/CT04/FF/2024/44422 dated 18.07.2024 on the subject mentioned above.

**Sir,**

Please refer to your application no. BIO/CT04/FF/2024/44422 dated 18.07.2024 received by this office on the above subject. In this regard, please find enclosed herewith permission to conduct a Phase IV clinical trial in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

You are required to comply with the requirements of Drugs and Cosmetics Rules, 1945 and communication of Central Licencing Authority.

Please acknowledge receipt of the same.

**Yours faithfully,**

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