

File No: BIO/CT/24/000027  
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 M/s Biological E. Limited, Plot No 1, Phase II, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana-500078, India to conduct Phase-IV clinical trial of the new drug or investigational new drug as per [Protocol no BECT087/PCV-Phase-IV\_SF/CTP-01, Version no. 1.0 dated 16.01.2024] in the below mentioned clinical trial sites.

**CT No.: CT- 06/2024**

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.

Place: New Delhi  
Date:

(Dr. Rajeev Singh Raghuvanshi)  
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) (14 Valent)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular Injection	
Composition:	Each dose of 0.5 mL contains	
	<b>Name of Ingredients</b>	<b>Quantity</b>
	Pneumococcal polysaccharide serotype 1	3.0 µg
	Pneumococcal polysaccharide serotype 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	2.2 µg
	Pneumococcal polysaccharide serotype 6B	4.4 µg
	Adsorbed onto Aluminium Phosphate, as Al <sup>+++</sup>	≤ 0.75 mg
	Polysaccharides conjugated to 20-50 µg of CRM <sub>197</sub>	
Indication(s):	For active immunization against invasive disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in infants from 6 weeks of age for 3 dose schedule.	

**Details of clinical trial sites-**

S. No.	Name and Address of Clinical Trial Sites	Ethics Committee details	Name of Principal Investigators
1	Belagavi Institute of Medical Sciences, BIMS building, 3 <sup>rd</sup> Floor, Dr B R Ambedkar Road, Belagavi - 590001, Karnataka, India.	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Dr B R Ambedkar Road, Belagavi (Belgaum) Karnataka – 590001, India. [ECR/801/Inst/KA/2016/RR-20]	Dr. Shailesh Patil
2	Cheluvamba Hospital, MMC & RI Irwin Road, Mysore - 570001, Karnataka, India.	IEC-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute, Irwin Road, Mysuru (Mysore) Karnataka – 570001, India. [ECR/134/Inst/KA/2013/RR-19]	Dr. Prashanth S
3	Jeevan Rekha Hospital, Opposite Civil Hospital, Dr. B R Ambedkar Road, Belagavi- 590002, Karnataka, India.	Ethics Committee Jeevan Rekha Hospital, Dr. B.R Ambedkar Road, Opp Civil Hospital, Belagavi (Belgaum), Karnataka – 590002, India. [ECR/1242/Inst/KA/2019/RR-22]	Dr. Abhishek T. Chavan

4	Jawahar Lal Nehru Medical College , Kala Bagh, Ajmer 305001, 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
5	JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, Karnataka, India.	Institutional Ethics Committee, JSS Medical College, Sri Shivarathreeshwara Nagara, Mysuru (Mysore), Karnataka - 570015, India.  [ECR/387/Inst/KA/2013/RR-22]	Dr. M. D. Ravi
6	Khalatkar Hospital, R-29, Reshimbag, Umred Road, Nagpur-440024, Maharashtra, India.	Khalatkar Hospital Ethics Committee, Khalatkar Hospital, R-29, Reshimbag, Umred Road, Nagpur, Maharashtra – 440024, India.  [ECR/1515/Inst/MH/2021]	Dr. Vasant Madhav Khalatkar
7	King George Hospital, Department of Pediatrics, 1 <sup>st</sup> Floor, Collectorate Junction, Maharani-peta, Visakhapatnam – 530002, Andhra Pradesh, India .	Institutional Ethics Committee, King George Hospital, Maharani-peta Near collector office junction, Visakhapatnam-530002, Andhra Pradesh, India.  [ECR/197/Inst/KGH/2013/RR-20]	Dr. B. S. Chakravarthy
8	KLEs Prabhakar Kore Hospital & Medical Research Centre, Sharawathi Ward Opposite Psychiatric ward, KLEs Dr Prabhakar Kore Hospital & MRC, Nehru Nagar, Belagavi - 590010, Karnataka, India.	Institutional Ethics Committee, KLE University, KLE Dr.PK Hospital and MRC, Nehru Nagar, Belagavi (Belgaum), Karnataka – 590010, India.  [ECR/211/Inst/KA/2013/RR-19]	Dr. N. S. Mahantshetti
9	Pt. B. D. Sharma Post Graduate Institute of Medical Sciences, University of Health Sciences, Rohtak, Haryana-124001, India.	Institutional Ethics Committee, Pt. BD Sharma, Post Graduate Institute of Sciences, PGIMS UHS Rohtak, Haryana -124001, India.  [ECR/293/Inst/HR/2013/RR-19]	Dr. Savita Verma
10	Prakhar Hospital Pvt. Ltd., 8/219, Khalasi Line, Arya Nagar, Kanpur, Uttar Pradesh-208002, India.	IEC Prakhar Hospital Pvt Ltd., 8/219 Arya Nagar, Kanpur Nagar, Uttar Pradesh – 208002, India.  [ECR/1017/Inst/UP/2017/RR-21]	Dr. V. N Tripathi

11	Sant Dnyaneshwar Medical Education & Research Centre, 695/A, Sadashiv Peth, Opp. Vijay Talkies, Pune-411030, Maharashtra, India.	Sant Dnyaneshwar Medical Education Research Centre, 695-A, Sadashiv Peth, Laxmi Road, opp. Vijay Talkies, Pune Maharashtra – 411030, India.  [ECR/127/Inst/MH/2013/RR-19]	Dr. Ashish Dhongade
12	St. Theresa's Hospital (STH), Erragadda Main Road, Czech Colony Sanath Nagar, Hyderabad - 500018 Telangana, India.	Ethics committee St Therasas Hospital, Sanathnagar, Opp. Erragadda, Raitu Bazar, Hyderabad, Telangana – 500018, India.  [ECR/230/Inst/AP/2013/RR-22]	Dr. G. Bala Kishor
13	Vignesh Women & Childrens Hospital, 32-6-18, Sikhamani Centre Rd, Mogalrajapuram, Kasturibaipet, Labbipet, Vijayawada, Andhra Pradesh-520010, India.	Institutional Ethics Committee, Anu Hospitals, Kovelamudivari Street Suryaraopet Vijayawada Krishna Andhra Pradesh – 520002, India.  [ECR/1049/Inst/AP/2018/RR-21]	Dr. Srimukhi Anumolu

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 Phase-IV multicentre follow-up study to assess the continued safety of Biological E’s 14-valent pneumococcal polysaccharide conjugate vaccine in subjects, who received 3-dose (3+0) primary PCV vaccination as part of BECT051 and BECT061 studies” [Protocol no. BECT087/PCV-Phase-IV\_SF/CTP-01, Version no. 1.0 dated 16.01.2024].
- II. To submit Ethics Committee approval for proposed Phase-IV Clinical trial.
- III. To submit Insurance Certificate for proposed Phase-IV Clinical trial

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

Place: New Delhi  
Date: