

File No: BIO/CT/23/000065  
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 No.: BECT081/PCV-Phase-IV/CTP-01, Version no.:1 dated 14.03.2023 in the below mentioned clinical trial sites.

**CT No.: CT- 08/2023**

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.

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:	Intramuscular injection	
Composition:	Each dose of 0.5 ml contains	
	Name of Active Ingredients	Quantity
	Pneumococcal polysaccharide serotype 1	3.0 µg
	Pneumococcal polysaccharide serotypes 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	2.2 µg
	Pneumococcal polysaccharide serotype 6B	4.4 µg
	Polysaccharides conjugated to 20 - 50 µg of CRM <sub>197</sub>	
	Inactive Ingredients	Quantity
	Adsorbed on Aluminum Phosphate Al+++	≤ 0.75 mg
	2- Phenoxyethanol	4 mg
Indication(s):	Immunization against invasive disease caused by Streptococcus pneumonia serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in 6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants	

**Details of clinical trial sites-**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Aditya multispecialty hospital, 13-4-64, 4th Lane, Gunturvari Thota, Kothapeta, Guntur 522001, Andhra Pradesh, India	Institutional Ethics Committee, Aditya Multi Speciality Hospital 13-3-52 , 3rd Line ,Gunturivari Thota, Kothapet Beside Peoples Trauma Guntur Andhra Pradesh - 522001 India [ECR/1347/Inst/AP/2020]	Dr.Nagarjuna Chadalavada
2	All India Institute Of Medical Sciences (AIIMS), Gate No, 1, Great Eastern Rd, opposite Gurudwara, AIIMS Campus, Tatibandh, Raipur 492099, Chhattisgarh	Institutional Ethics Committee, AIIMS RAIPUR Room no. 2103, 2nd Floor South Wing Medical College Complex, Gate No. 5 All India Institute of Medical Sciences, Tatibandh, GE Road, Raipur, 492099, Chhattisgarh, India. [ECR/714/Inst/CT/2015/RR-21]	Dr.Atul Jindal
3	All India Institute of Medical Sciences (AIIMS), MIHAN, Nagpur 441108, Sumthana, Maharashtra	Institutional Ethics Committee for Clinical Trial All India Institute of Medical Sciences, Nagpur M/S Director AIIMS, Plot No 2, Sector 20 1st floor, OPD building, MIHAN, Nagpur, Maharashtra - 441108 [ECR/1392/Inst/MH/2020]	Dr.Urmila Chauhan

4	All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar 751019, Odisha, India	Institutional Ethics Committee, All India Institute of Medical Sciences, BBSR AIIMS Bhubaneswar Sijua P/O Patrapada, Bhubaneswar Khordha Orissa - 751019 India [ECR/534/Inst/OD/2014/RR-20]	Dr. Bhagirathi Dwibedi
5	Bangalore Medical College and Research Institute, Fort, Krishna Rajendra Rd, Bengaluru 560002, Karnataka, India	Ethics Committee, Bangalore Medical College And Research Institute, Fort K R Road Bengaluru, (Bangalore) Urban Karnataka - 560002 India [ECR/302/Inst/KA/2013/RR-20]	Dr.Mallesha.K
6	BAPS Pramukh Swami Hospital, Shri Pramukh Swami Maharaj Marg, Adajancharasta. Adajan. Surat- 395 009, Gujarat, India	Institutional Ethics Committee, BAPS Pramukh Swami Hospital Adajan Cross Road, Adajan Surat Gujarat - 395009 India [ECR/639/Inst/GJ/ 2014/RR-20]	Dr. Kiritkumar Jesabhai Sisodiya
7	Belagavi Institute Of Medical Sciences, Dr B R Ambedkar Rd, Sadashiv Nagar, Belgaum 590019, 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 Chinmayi Joshi
8	BGS Global Institute of Medical Sciences, Dr.Vishnuvardhan Rd, Kengeri, Bengaluru 560060, Karnataka, India.	Institutional 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 Uttarahalli Road, Kengeri Bangalore South Karnataka, Bengaluru (Bangalore) Urban Karnataka - 560060 India [ECR/1307/Inst/KA/2019]	Dr.Ramesh.M
9	Chettinad Hospital and Research Institute, SH 49A, Kelambakkam, Chennai 603103, Tamil Nadu, India	Institutional Ethics Committee, Chettinad Academy of Research and Education, Rajiv Gandhi Salai, Kelambakkam, Dist: Kanchipuram, Chennai-603103 [ECR/212/Inst/TN/2013/RR-19]	Dr.M.Alexander
10	Chirayu Hospital, Kalwar Rd, Hathoj, Jaipur 302012, Rajasthan, India	Chirayu Hospital -A Unit Of KSCH Pvt. Ltd Kalwar Road Hathoj, Jaipur Rajasthan – 302012 India [ECR/1582/Inst/RJ/2021]	Dr.Kishori Sharan Agarwal
11	Gillurkar Multispeciality Hospital, 20, Reshimbag, Umred Road, Nagpur 440009, Maharashtra, India	Ethics Committee, Gillurkar Multispecialty Hospital, Plot no. 20, Reshimbag Umred Road ,Nagpur Maharashtra - 440009 India [ECR/1374/Inst/MH/2020]	Dr.Girish.P.Charde

12	Government Medical College & Hospital, University Rd, Jubilee Park, Aurangabad 431004, Maharashtra, India	Institutional Ethics Committee Government Medical College Aurangabad Ethics committee, Department of Pharmacology Government Medical College, Aurangabad, Maharashtra – 431001 [ECR/314/Inst/MH/2013/RR-19]	Dr.Prabha Khaire
13	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,
14	JLN 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
15	JSS Hospital, Mahatma Gandhi Road, Fort Mohalla, Mysuru-570004, Karnataka, India	Institutional Ethics Committee, JSS Medical College, JSS Hospital, Mysore, JSS Medical College, Sri Shivarathreeshwara Nagara, Mysore, Karnataka – 570015 [ECR/387/Inst/KA/2013/RR-22]	Dr. M.D.Ravi
16	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
17	Latha Mangeshkar Hospital Maharajbagh Rd, Sitabuldi, Nagpur - 440012, Maharashtra, India	Institutional Ethics Committee, NKP Salve Institute of Medical Sciences, Digdoh Hills Hingna road, Nagpur Maharashtra-440019 [ECR/88/Inst/MH/2013/RR-19]	Dr. Anju J.K Mehrotra
18	Mahatma Gandhi Institute of Medical Sciences (MGIMS), Sewagram, Wardha 442102, Maharashtra, India	Institutional Ethics Committee (Department of Pharmacology), Mahatma Gandhi Institute of Medical sciences, Sevagram Wardha Maharashtra - 442102 [ECR/47/Inst/MH/2013/RR-19]	Dr. Bishan Swarup Garg
19	Medipoint Hospital, 3rd Floor, Nagaras Road, DP Road, Near Kumar Padmalaya, Aundh, Pune 411007, Maharashtra, India	Penta-Med Ethics Committee, Medipoint Hospitals Pvt. Ltd 241/1, New D.P.Road, Near Sai Heritage, Aundh Pune Maharashtra - 411007 [ECR/357/Inst/MH/2013/RR-20]	Dr.Jog Pramod Prabhakar

20	Medstar Speciality Hospital, 641/17/1/3, Kodigehalli Main Rd, Sahakar Nagar, Sanjeevini Nagar, Bengaluru 560092, Karnataka, India	Ethics Committee Medstar Speciality Hospital No 614, 17/1/3, Kodigehalli Main Road sahakarnagar Post Bangalore Bengaluru (Bangalore) Urban Karnataka - 560092 India' [ECR/1324/Inst/KA/2019]	Dr.Prashanth.M.V
21	Panimalar Medical College Hospital & Research Institute, Varadharajapuram, Chennai Outer Ring Rd, Poonamallee, Chennai, 600123 Tamil Nadu, India	Institutional Ethics Committee Panimalar Medical College Hospital and Ri Varadharajapuram Poonamallee Chennai, Tiruvallur Tamil Nadu- 600123 India' [ECR/1399/Inst/TN/2020]	Dr Ramanath Andy Karayar
22	Priya Children's Hospital, D.No. 57, 12-3, Panta Kaluva Rd, Maruti Colony, New P & T Colony, Patamata, Vijayawada 520010, Andhra Pradesh	Institutional Ethics Committee Anu Hospitals Kovelamudivari Street Suryaraopet Vijayawada Krishna Andhra Pradesh - 520002 India [ECR/1049/Inst/AP/2018/RR-21]	Dr.B.Sudhakar
23	PT. B D Sharma Post Graduate Institute of Medical Sciences & Hospital Rohtak - 124001, Haryana, India	Institutional Ethics Committee, PGIMS UHS Rohtak Pt. BD Sharma, Post Graduate Institute Of Sciences PGIMS UHS Rohtak-124001, Haryana 124001 India [ECR/293/Inst/HR/2013/RR-19]	Dr. Savita Verma
24	Rajarajeshwari Hospital, No.202, Kambipura, Mysore Road, Bengaluru-560 074, Karnataka, India	Institutional Ethics Committee, Rajarajeswari Medical College and Hospital No. 202, Kambipura, Mysore Road, Bengaluru-560 074, Karnataka, India [ECR/56/Inst/KA/2013/RR-19]	Dr. Prema.R
25	SSG General Hospital, Anandpura, Vadodara 390001, Gujarat, India	Institutional Ethics Committee for Human Research, Medical College, Baroda Anandpura Vadodara 390001, Gujarat, India [ECR/85/Inst/GJ/2013/RR-19]	Dr.Pareshkumar.A.T hakkar
26	Subham Sudbhawana super speciality Hospital, B31/80, 23-Bhogabir, Lanka Varanasi-221005. Uttar Pradesh	Ethics Committee, Shubham Sudbhawana Superspeciality Hospital B 31/80, 23B - Bhogabeer, Lanka, Varanasi, Uttar Pradesh - 221005 India [ECR/667/Inst/UP/2014/RR-20]	Dr.Madhukar Pandey
27	King George Hospital Collectorate Junction, Maharanipecta, Visakhapatnam -530002 Andhra Pradesh, India	Institutional Ethics Committee, King George Hospital Collectorate Office Junction, Visakhapatnam -530002 Andhra Pradesh, India [ECR/197/Inst/KGH/2013/RR-20]	Dr. B.S Chakravarthy.

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 multicentre Phase-IV study to evaluate the safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine when administered in 6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants vide protocol no: BECT081/PCV-Phase-IV/CTP-01, Version no: 1 dated 14.03.2023.
- 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. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi  
Date:

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

