

File No: BIO/CT/20/000187

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 Tergene Biotech Private Limited ,Suite 121 & 122, Building 450, Genome Valley, Turkapally (V), Shamirpet (M), RR Dist, HYDERABAD (India) - 500078 Telephone No.: 9959013131 FAX: 40-23480075 E-Mail : ksathyan@gmail.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol no.: CBCC/2020/029 Version number:1.0,09/Nov/2020** in the below mentioned clinical trial sites.

**CT No.: CT- 07/2021**

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.

Date : 25-MAR-2021  
Place: New Delhi

(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), I.P. (15 valent )	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for Injection for Intramuscular (IM) route of administration	
Composition:	Each 0.5 mL Contains:	
	*Pneumococcal polysaccharide for serotypes 1, 2, 3, 4, 5, 6A, 7F, 9V, 12F, 14, 18C, 19A, 19F & 23F and for serotype 6B	2.2 µg
	*Pneumococcal polysaccharide for serotype 6B	4.4 µg
	*Conjugated to CRM197 carrier protein (~35 µg) and adsorbed on aluminium phosphate (0.125 mg aluminium)	
	Phenoxyethanol	5 mg
	Polysorbate 80	0.1 mg
	Sodium chloride	4.5 mg
	Water for injection	q.s to 0.5ml
Indications:	Active immunization of infants and children from 6 weeks up to 5years of age against Invasive Pneumococcal Disease caused by Streptococcus pneumonia serotypes 1, 2, 3, 4, 5, 6A, 6B, 7F, 9V, 12F, 14, 18C, 19A, 19F, 23F and for serotype 6B.	

**Details of clinical trial sites-**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	KLE'S Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belgaum 590010, Karnataka, I	Institutional Ethics Committee, KLE University, Belgaum Karnataka - 590010 ECR/211/Inst/KA/2013/RR-19	Dr. Mahantesh Patil
2	Acharya Vinoba Bhave Rural Hospital, Wardha Sawangi (Meghe), 442004, Maharashtra, India.	Institutional Ethics Committee, Datta Meghe Institute of Medical Science, Wardha Maharashtra – 442004. ECR/440/Inst/MH/2013/RR-19	Dr Ashish Varma
3	Suyog Hospital, Nashik 2 <sup>nd</sup> Floor, B-Wing, Krushi Utpanna Bazar, Samiti Sankul, Dindori Rd, Panchavati, Nashik - 422003, Maharashtra, India	Institutional Ethics Committee, Suyog Hospital, 2nd Floor, B-Wing Krushi Utpanna Bazar Samiti Sankul, Dindori Road Panchavati Maharashtra- 422003 ECR/965/Inst/MH/2017/RR-2020	Dr. Reena Rathi
4	All India Institute of Medical Science, Great Eastern Road, Tatibandh, Raipur, Chhattisgarh 492099, India	Institute Ethics Committee, All India Institute of Medical Sciences, Department of Pharmacology, 2 <sup>nd</sup> Floor, South Wing, Medical College Complex, Gate No.5, Tatibandh, GE Road, Raipur	Dr. Atul Jindal

		Chhattishgarh ECR/714/Inst/CT/2015/RR-18	
5	Grant Government Medical College and Sir J.J. Group of Hospitals, Nagpada Mumbai Central, Near Sandhurst Road and JJ Police Station, Mumbai – 400008, Maharashtra, India	Institutional ethics committee, Grant Government Medical College and Sir J.J. Group of Hospitals, Nagpada Mumbai Central, Near Sandhurst Road and JJ Police Station, Mumbai – 400008, Maharashtra, India ECR/382/Inst/MH/2013/RR-19	Dr. Sushant Mane
6	Medstar Speciality Hospital, #641/17/1/3, Kodigehalli Main Road, Sahakarnagar, Bangalore-560092.	Medstar Speciality Hospital Ethics Committee Medstar Speciality Hospital, 641-17-1-3, Kodigehalli Main Road, Sahakarnagar, Bengaluru -560092 Bengaluru Karnataka ECR/1324/Inst/KA/2019	Dr. Prashanth. M. V
7	Cheluvamba Hospital, Mysore Department of Paediatrics Mysore, Karnataka,	Institutional ethics committee, Mysore Medical college and Research Institute and Associate Hospitals, Irwin Road, Mysore Karnataka – 570001 ECR/134/Inst/KA/2013/RR-19	Dr. Pradeep. N
8	Belagavi Institute of Medical Sciences (BIMS), Dr. Ambedkar Road, Belgaum-590010, Karnataka, India.	Institutional Ethics Committee, Belagavi Institute of Medical Sciences (BIMS), Dr. Ambedkar Road, Belgaum-590010, Karnataka, India. ECR/801/Inst/KA/2016/RR-20	Dr. Meenakshi. R
9	Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune-411018, Maharashtra, India	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune- 411018, Maharashtra, India ECR/1236/Inst/MH/2019	Dr. Deepali Ambike
10	Lifepoint Multispeciality Hospital, Sr. No. 145/1 Mumbai Bypass Rd, Pimpri-Chinchwad, 411023, Maharashtra, India.	Ethics Committee, Lifepoint Multispeciality Hospital, Sr. No. 145/1 Mumbai Bypass Rd, Pimpri-Chinchwad, 411023, Maharashtra, India. ECR/751/Inst/MH/2015/RR18	Dr Swapnil Janbandhu
11	Government Medical College and Hospital, Near Hanuman Nagar Nagpur- 440009 Maharashtra, India	Institutional Ethics Committee, Government Medical College and Hospital, Near Hanuman Nagar Nagpur- 440009 Maharashtra, India ECR/43/Inst/MH/2013/RR-19	Dr. Avinash Gawande
12	Sudbhawana Hospital, Varanasi B31/80-23b, Bhogabir, Lanka, Varanasi-221005, Uttar Pradesh, India	Sudbhawana Hospital Ethics Committee, Sudbhawana Hospital, B-31/80-23B Bhogabir Lanka, Varanasi Uttar Pradesh -221005 ECR/667/Inst/UP/2014/RR-17	Dr. Madhukar Pandey

13	Mahatma Gandhi Mission Medical College & Hospital, Aurangabad N-6, CIDCO, Aurangabad-431003, Maharashtra, India	MGM Ethics Committee for Research on Human subject, Mahatma Gandhi Mission Medical College & Hospital, Aurangabad N-6, CIDCO, Aurangabad-431003, Maharashtra, India ECR/581/Inst/MH/2014/RR-20	Dr. Haseeb Mohammad
14	G.S.V.M. Medical College, Kanpur Department of Pediatric, Swaroop Nagar, Kanpur-208002, Uttar Pradesh, India	G.S.V.M. Medical College, Kanpur Department of Pediatric, Swaroop Nagar, Kanpur-208002, Uttar Pradesh, India ECR/680/Inst/UP/2014/RR-20	Dr. Rupa Singh Dalmia
15	Niloufer Hospital, Red Hills, Lakdikapul, Hyderabad-500004, Telangana, India	Institutional Ethics Committee, Niloufer Hospital, Red Hills, Lakdikapul, Hyderabad-500004, Telangana, India ECR/300/Inst/AP/2013/RR-19	Dr. N. Ravi Kumar
16	St. Theresa's Hospital, Hyderabad, Sanath Nagar, Hyderabad-500018, Telangana, India	Ethics Committee, St. Theresa's Hospital, Hyderabad, Sanath Nagar, Hyderabad - 500018, Telangana, India ECR/230/Inst/AP/2013/RR-19	Dr. G. Bala Kishor
17	All India Institute of Medical Sciences (AIIMS), Patna Phulwari Sharif, Patna-801507, Bihar, India	Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), Patna Phulwari Sharif, Patna-801507, Bihar, India ECR/1387/Inst/BR/2020	Dr. Chandramani Singh
18	Jeevan Rekha Hospital, Opp. Civil Hospital, Dr. B. R. Ambedkar Road, Belagavi-590002, Karnataka, India. ECR/1242/Inst/KA/2019	Institutional Ethics Committee, Jeevan Rekha Hospital, Opp. Civil Hospital, Dr. B. R. Ambedkar Road, Belagavi-590002, Karnataka, India. ECR/1242/Inst/KA/2019	Dr. Abhishek Chavan
19	Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur-208002, Uttar Pradesh, India.	Institutional Ethics Committee, Prakhar Hospital Pvt. Ltd. 8/219, Arya Nagar, Kanpur-208002, Uttar Pradesh, India. ECR/1017/Inst/UP/2017	Dr. Virendra Nath Tripathi
20	Sri Ramachandra Institute of Higher Education and Research (SRIHER) No.1, Ramachandra Nagar, Porur, Chennai-600116, TamilNadu, India.	Institutional Ethics Committee, Sri Ramachandra Institute of Higher Education and Research (SRIHER) No.1, Ramachandra Nagar, Porur, Chennai-600116, TamilNadu, India. ECR/203/Inst/TN/2013/RR-19	Dr. Padmasani Venkat Ramanan
21	SSG Hospital Anandpura, Vadodara - 390001, Gujarat, India.	Institutional Ethics Committee on Human Research, Department of Pediatrics, Ward 17, First Floor, Medical College & SSG Hospital, Vadodara India 390001, Gujarat, India ECR/85/Inst/GJ/2013/RR-19	Dr. Paresh A. Thakkar

22	JSS Hospital, Mahatma Gandhi Road, Fort Mohalla, Mysore-570004, Karnataka, India.	Institutional Ethics Committee, JSS Medical College & Hospital, 3 <sup>rd</sup> Floor, JSS Medical College, Mysore Karnataka - 570015 ECR/387/Inst/KA/2013/RR-19	Dr. Deepti Thandaveshwar a
23	IMS & SUM Hospital, K-8 Lane 1, Kalinganagar, Ghatikia, Bhubaneswar-751003, Odisha, India. ECR/627/Inst/OR/2014/RR-20	Ethics Committee, Institute of Medical Sciences (IMS) and SUM Hospital, S 'O' A University, K8, Kalinga Nagar, Bhubaneswar Orissa – 751003 ECR/627/Inst/OR/2014/RR-20	Dr. Dillip Kumar Dash
24	All India Institute of Medical Sciences (AIIMS), Bhubaneswar Sijua, Patrapada, Bhubaneswar-751019, Odisha, India. ECR/534/Inst/OD/2014/RR-20	Institutional Ethics Committee, All India Institute of Medical sciences situated at Village Sijua, Patrapada, PO Dumduma, Bhubaneswar Orissa - 751019 ECR/534/Inst/OD/2014/RR-20	Dr. Rashmi Ranjan Das
25	Maharshi Child Hospital, A-45, Subhash Nagar Shopping Center, Jaipur-302016, Rajasthan, India	Maharshi Child Hospital, A-45, Subhash Nagar Shopping Center, Jaipur-302016, Rajasthan, India ECR/3/Inst/RJ/2013/RR-16	Dr. Pawan Sharma

In addition to point 3, the permission is subject to following condition(s):

- I. The Phase III clinical trial should be conducted as per title “A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given with Routine Pediatric Vaccinations” & Protocol Number –CBCC/2020/029, Version number:1.0, 09/Nov/2020.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. The firm is required to submit Contract with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator before initiation of clinical trial.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Date: 25-MAR-2021  
Place: New Delhi

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