

File No: BIO/CT/23/000101
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 Novo Medi Sciences Private Limited, Ground Floor & 1st Floor Plot No. 133 to 154, Jawahar CO-OP Industrial Estate Ltd. Kamothe, Raigad, Panvel, Maharashtra- 410209, India to conduct Phase-III clinical trial of the new drug or investigational new drug as per [Protocol no. CRNI/CTP/018, Version no. 2.0 dated 04.11.2023] in the below mentioned clinical trial sites.

CT No.: CT- 09/2024

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:	13-valent Pneumococcal Polysaccharide Conjugate Vaccine (TT/DT)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular injection	
Composition:	Each dose of 0.5 ml contains	
	Name of Ingredients	Quantity
	Active Ingredients	
	Pneumococcal polysaccharide serotype 1	1.8 µg
	Pneumococcal polysaccharide serotype 3	2.1 µg
	Pneumococcal polysaccharide serotype 4	2.1 µg
	Pneumococcal polysaccharide serotype 5	1.75 µg
	Pneumococcal polysaccharide serotype 6A	1.85 µg
	Pneumococcal polysaccharide serotype 6B	4.4 µg
	Pneumococcal polysaccharide serotype 7F	1.75 µg
	Pneumococcal polysaccharide serotype 9V	2.3 µg
	Pneumococcal polysaccharide serotype 14	1.35 µg
	Pneumococcal polysaccharide serotype 18C	3.65 µg
	Pneumococcal polysaccharide serotype 19A	1.6 µg
	Pneumococcal polysaccharide serotype 19F	1.25 µg
	Pneumococcal polysaccharide serotype 23F	2.35 µg
	Inactive Ingredients	
	Sodium Chloride	4.25 mg
Aluminium Phosphate	0.1 mg	
Polysorbate 80	0.1 mg	
Succinic acid	0.295 mg	
Water for injection	0.495 ml	
Indication(s):	<p>For active immunization for the prevention of disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in infants from 6 weeks to 8 weeks and children and adults 6 years to 65 years.</p> <p>In infants (6-8 weeks): 3 doses at interval of 4 weeks.</p> <p>In children and adults (6 years to 65 years): Single dose.</p>	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Sites	Ethics Committee details	Name of Principal Investigators
1.	Dept. of Community Medicine, All India Institute of Medical Sciences, Patna Bihar- 801507.	Institutional Ethics Committee, All India Institute of Medical Sciences, Patna, Phulwari Sarif, Patna, Bihar -801507, India. [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
2.	Jeevan Rekha Hospital, Dr. B R Ambedkar Road, Belagavi, Karnataka- 590010	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B. R. Ambedkar Road, Opp. Civil Hospital, Belagavi, Karnataka – 590002, India. [ECR/1242/Inst/KA/2019/RR-22]	Dr. Abhishek T. Chavan

3.	PKTB Hospital, Mysore Medical College and Research Institute, KRS Road, Kumbarakoppal, Gokulam, Mysuru-570002	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 C
4.	Uttar Pradesh University of Medical Sciences, Saifai, Etawah, UP.	IEC Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh-206130. [ECR/1830/Inst/UP/2023]	Dr. Dinesh Kumar
5.	Dr. D. Y. Patil Medical College, Hospital and Research Centre, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra-411018	Ethics Committee Dr. D Y. Patil Vidyapeeth, Sant Tukaram Nagar, Pimpri, Pune Maharashtra-411018. [ECR/361/Inst/MH/2013/RR-24]	Dr. Srikanth Tripathy
6.	Govt. Medical College & Govt. General Hospital (Old RIMSGGH), Srikakulam-532001, Andhra Pradesh, India	Institutional Ethics Committee, Govt. Medical College & Govt. General Hospital, Srikakulam-532001, Andhra Pradesh, India. [ECR/492/Inst/AP/2013/RR-20]	Dr. K. Sunil Naik
7.	AIIMS, Sijua, Patrapada, Bhubaneswar-751019, Odisha, India.	Institutional Ethics Committee, AIIMS, Sijua, Patrapada, Bhubaneswar - 751019, Odisha, India. [ECR/534/Inst/OD/2014/RR-20]	Dr. Bagirathi Dwibedi
8.	Rajarshee Chhatrapati Shahu Maharaj Government Medical College and Chhatrapati Pramila Raje General Hospital, Dasara Chowk, Bhausinghaji Road, Town Hall, Kolhapur-416012, Maharashtra, India.	Rajarshee Chhatrapati Shahu Maharaj Government Medical College & Chhatrapati Pramila Raje Hospital, Kolhapur Institutional Ethics Committee, Building No.2, Quarter No.3, Room No. 7, Dassara Chowk, Kolhapur, Maharashtra-416007, India. [ECR/703/Inst/MH/2015/RR-20]	Dr. Vijaykumar Bhagwan Barge

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, randomized, double-blind, multi-center, phase III study to assess and compare the immunogenicity and safety of the 13-valent Pneumococcal Polysaccharide Conjugate Vaccine in healthy Indian subjects." [Protocol no. CRNI/CTP/018, Version no. 2.0 dated 04.11.2023].

- II. Firm is required to constitute a DSMB to review the safety data.
- III. Firm is required to submit Ethics Committee approval for Phase-III clinical trial.
- IV. The formulation intended to be used in the Phase-III clinical trial shall be manufactured under GMP conditions.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date:

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
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