

File No: BIO/CT/19/000053
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 Licensing Authority hereby permits M/s Serum Institute of India Pvt. Ltd. (SIPL) 212/2, Off Soli Poonawalla Road, Hadapsar, Pune -411028, India. Tel: + 91-20-26602451 Fax: + 91-20-26993921 to conduct clinical trial of the new drug or investigational new drug as per protocol number ACYWX-04 Version: 02, dated 18 September 2019 Amendment: 01 in the below mentioned clinical trial sites.

CT No.: CT- 27/2019

1. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
2. 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: 10-DEC-2019

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Annexure:**Details of new drug or investigational new drug:**

Names of the new drug or investigational new drug:	Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze Dried)	
Therapeutic class:	Vaccine	
Dosage form:	Lyophilized Powder for reconstitution	
Composition:	Single Dose Vial presentation	
	Each dose of 0.5 ml when reconstituted Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine contains:	
	components	Qty.
	Meningococcal group A1	5 µg
	Meningococcal group C2	5 µg
	Meningococcal group Y2	5 µg
	Meningococcal group W2	5 µg
	Meningococcal group X 1	5 µg
	Sucrose	11.90mg
	Sodium citrate (dihydrate)	1.98 mg
	Tris (Trometamol)	0.48 mg
	Tetanus Toxoid	7.8 to 33.4 µg
	CRM ₁₉₇	11.7 to 50.1 µg
¹ each polysaccharide conjugated to Tetanus Toxoid; ² each polysaccharide conjugated to CRM ₁₉₇		
Diluent: 0.9 % Sodium Chloride Injection IP. (Mfg by Sovereign Pharma Pvt. Ltd. (SPPL) Nani Daman – 396210)		
Indications:	Active immunization against invasive meningococcal disease caused by <i>meningococcus</i> serogroups A, C, Y, W and X.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Jhangir Clinical Development Centre Pvt. Ltd., Jhangir Hospital Premises, 32 Sassoon Road, Pune - 411001, Maharashtra	Ethics Committee Jhangir Clinical Development Centre Pvt. Ltd. Jhangir Hospital Premises 32, Sassoon Road, Pune 411 001	Dr. Kiranjit Singh
2	Hamdard Institute of Medical Sciences and Research (HIMSR), and Associated Hakeem Abdul Hameed Centenary Hospital (HAHCH) Jamia Hamdard, Hamdard Nagar, New Delhi 110062	Jamia Hamdard Institutional Ethics Committee, Basement, Nano Biotechnology Building, Jamia Hamdard, Hamdard Nagar, New Delhi -11 0062 ECR/48/Inst/DL/2013/RR-19	Dr. Sunil Kohli,
3	KEM Hospital Research Centre, Vadu Rural Health Program, Vadu Budruk, Taluka- Shirur, District Pune - 412216, Maharashtra, India	KEM Hospital Research Centre Ethics Committee, Sardar Moodliar Road, Rasta Peth. Pune-411011, Maharashtra, India	Dr. Anand Kawade
4	Seth G S Medical College & KEM Hospital, Parel, Mumbai - 400 012, Maharashtra	Institutional Ethics Committee 2, Seth GS Medical College & KEM Hospital, Dr. S.S. Rao Marg, Parel, Mumbai- 400012, Maharashtra, India	Dr. Nithya Gogtay

5	TN Medical College & BYL Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai – 400008, Maharashtra	Institutional Ethics Committee, Topiwala National Medical College and B.Y. L. Nair Charitable Hospital, Ground Floor G Building, A.L. Nair Road, Mumbai Central, Mumbai -400008, Maharashtra.	Dr. Renuka Munshi
6	Post Graduate Institute of Medical Education and Research (PGIMER), Sector - 12, Chandigarh -160 012, India	Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh -160 012	Dr Madhu Gupta
7	Sri Ramachandra Institute of Higher Education and Research (DU), Clinical Research Division, Dental College Basement, No. 1, Ramachandra Nagar, Porur, Chennai – 600116, Tamilnadu	Institutional Ethics Committee Sri Ramachandra Institute for Higher Education and Research (SRIHER), Porur, Chennai -600116	Dr. K. Vengadakrishnan
8	Dr Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences and Kasturba Hospital, Sewagram, Wardha - 442102, Maharashtra	Institutional Ethics Committee, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha- 442102, Maharashtra, India	Dr Chetna Maliye
9	Kempegowda Institute of Medical Sciences (KIMS) Hospital & Research Centre, K. R. Road, V. V. Puram, Bangalore 560004, Karnataka	KIMS Institutional Ethics Committee Kempegowda Institute of Medical Sciences (KIMS), Banashankari II Stage, Bangalore - 560070, Karnataka	Dr Ravish H S
10	M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore – 560054, Karnataka	Ethics Committee M. S Ramaiah Medical College and Hospitals M S. Ramaiah Nagar, MSRIT Post, Bangalore -560054 , Karnataka.	Dr Anil Kumar T
11	Institute of Medical Sciences and SUM Hospital, K8 Kalinganagar, Bhubaneswar, Orissa – 751003.	EC, IMS and SUM Hospital IMS and SUM Hospital, K8, Kalinganagar, Bhubaneswar, Khordha, Orissa - 751003, India	Dr Sandeep Kumar Panigrahi

In addition to point 2, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled “A Phase II/III, Randomized, Observer-blind, Controlled, Multi-Center Study to Evaluate the Lot to Lot Consistency of SIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) and to Compare its Safety and Immunogenicity with that of Licensed Meningococcal ACWY Vaccine Menactra® in Healthy Individuals 18-85 Years of Age.” vide protocol number: ACYWX-04, Version No.: 2.0, Dated 18-Sept-2019 Amendment: 01.
- II. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- III. Process validation of the CT batches before the initiation of Phase-III CT shall be carried out and the specification of free polysaccharide stated to be 40% should be tightened in line with international practices.

(Dr. V. G. Somani)

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