

File No: BIO/CT/19/000104
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 Dr. Rahul Shashidhar Kulkarni of M/s Sanofi Healthcare India Private Limited, Sanofi House, C.T.S-117B, L & T BUSINESS PARK, Saki Vihar Road, Powai Mumbai (India) - 400072 to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: SH600004 - Version 1.0 dated 08 November 2019** in the below mentioned clinical trial sites.

CT No.: CT- 03/2020

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: 21-FEB-2020

(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:	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA), Haemophilus influenzae Type b Conjugate and Poliomyelitis (Inactivated) Vaccine (Adsorbed)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid (injection)	
Composition:	Each dose of 0.5 ml contains	
	Name of Active ingredient	Quantity
	Poliomyelitis Virus (Inactivated) Type 3 (Saukett Strain)	32.0 D antigen Units
	Poliomyelitis Virus (Inactivated) Type 2 (MEF-1 Strain)	8.0 D antigen Units
	Poliomyelitis Virus (Inactivated) Type 1 (Mahoney Strain)	40.0 D antigen Units
	Purified capsular polysaccharide of Hib conjugated to 20-40 mcg of Tetanus Toxoid (Carrier protein)	12.0 µg
	rDNA Hepatitis B Surface Antigen	10.0 µg
	B. Pertussis (Whole cell)	≥4.0 IU
	Tetanus Toxoid	≥60.0 IU
	Diphtheria Toxoid	≥30.0 IU
	Aluminium Phosphate gel eq. to Al +++	0.625 mg
	2-Phenoxyethanol (2-PE)	0.6% v/v
	Formaldehyde	6.25 µg
	Sodium Chloride	4.5 mg
Indication(s):	Water for injection	q.s. to 0.5 mL
	For active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis-B, invasive Haemophilus influenzae Type b and Poliomyelitis diseases	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Maulana Azad Medical College, & Associated Lok Nayak Hospital, Bahadur Shah Zafar Marg, New Delhi-110002.	Institutional Ethics Committee, Maulana Azad Medical College & Associated Lok Nayak Hospital, Bahadur Shah Zafar Marg, New Delhi-110002	Dr. Raghvendra Singh
2	Institute of Child Health, Dr. Brijesh Guha Street, Kolkata West Bengal – 700017	Institutional Ethics Committee, Institute of Child Health, Dr. Brijesh Guha Street, Kolkata West Bengal – 700017	Dr Monjori Mitra
3	JSS Medical College & Hospital, Institutional Ethics Committee, JSS Medical College & Hospital, 3rd Floor, JSS Medical College, Mysore Karnataka – 570015.	Institutional Ethics Committee, JSS Medical College and Hospital, 3rd floor, JSS Medical College, Mysore-570015, Karnataka. ECR/387/Inst/KA/2013/RR-19	Dr. Mandyam Dhati Ravi

4	Cheluvamba Hospital, Mysore Medical college and Research Institute and Associate Hospitals, Irwin Road, Mysore Karnataka – 570021	Institutional Ethics Committee, Mysore Medical college and Research Institute and Associate Hospitals, Irwin Road, Mysore Karnataka – 570021	Dr. Prashanth S,
5	Kasturba Medical College, Department of Community Medicine, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Udupi, Karnataka – 576104.	Institutional Ethics Committee, Kasturba Hospital. Manipal, Udupi, Karnataka – 576104.	Dr Ranjitha Shetty
6	Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital, Pune-Satara Road, Pune Maharashtra 411043	Institutional Ethics Committee, Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital, Pune-Satara Road, Pune Maharashtra 411043	Dr. Sonali Palkar
7	KEM Hospital, Department of Clinical Pharmacology Seth GS Medical College & King Edward Memorial Hospital, Mumbai Maharashtra 400012, India.	Institutional Ethics Committee, KEM Hospital, Department of Clinical Pharmacology Seth GS Medical College & King Edward Memorial Hospital, Mumbai Maharashtra 400012, India.	Dr Nithya Gogtay
8	Shirdi Sai Baba Rural Hospital King Edward Memorial Hospital Research Centre, Vadu Rural Health Program, Village -Vadu (Budruk), Tal-Shirur, Pune-412216	King Edward Memorial Hospital Research Centre Ethics Committee, Sardar Moodliar Road, Rasta Peth Pune, Maharashtra 411011	Dr Anand Kawade
9	Govt. Victoria Hospital Chengala Rao Peta, Purna Market, Visakhapatnam, Andhra Pradesh-530001	Institutional Ethics Committee, King George Hospital Vishakhapatnam, Andhra Pradesh 530001	Dr. I.V. Padmavathi

In addition to point 3, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled "Phase III, randomized, open-label, multicenter study evaluating the immunogenicity and safety of Shan6 vaccine administered, concomitantly with or without Measles-Mumps Rubella (MMR) vaccine, to healthy toddlers in India vide Protocol no. - Version 1.0 dated 08 November 2019".
- II. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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