

File No: BIO/CT/19/000063
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 Protocol No.: SII-wHEXA/IN-02, Version No.: 1.0, Protocol Date 02-MAY-2019 in the below mentioned clinical trial sites.

CT No.: CT- 25/2019

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: 14-NOV-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:	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B, Poliomyelitis (inactivated) and Haemophilus Influenzae Type b conjugate Vaccine (Adsorbed) [DTwPHepB-IPV-Hib vaccine (Adsorbed)]
Therapeutic class:	Vaccine
Dosage form:	Liquid
Composition:	Each dose of 0.5 mL of vaccine contains: Diphtheria Toxoid..... ≥ 30 IU Tetanus Toxoid..... ≥ 40 IU B. Pertussis (Whole cell)..... ≥ 4 IU HBsAg (rDNA)..... ≥ 10 mcg Inactivated Polio Vaccine (Salk strains grown on vero cells) Type -1..... 40 DU Type -2..... 8 DU Type -3..... 32 DU Hib conjugate (PRP-TT)..... 10 mcg Aluminium (Al ⁺⁺⁺)..... 0.28 mg (As Aluminium Phosphate gel) 2- Phenoxyethanol..... 0.5 %
Indications:	Active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliovirus type 1, 2 & 3 and Haemophilus Influenzae type b. Recommended schedule for primary immunization in infants is three doses with an interval of 4 weeks between doses, starting at 6 weeks of age. A booster dose is recommended in the second year of life.

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	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 ECR/272/Inst/MH/2013	Dr. Anand Kawade
2	Maulana Azad Medical College & Associated Lok Nayak Hospital, Bahadur Shah Zafar Marg, New Delhi-110002, India.	Institutional Ethics Committee, Maulana Azad Medical College & Associated Lok Nayak Govind Ballabh Pant Hospitals Bahadur Shah Zafar Marg, New Delhi-110002, India ECR/329/Inst/DL/2013/RR-16	Dr. Anurag Agarwal
3	Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata-700017, West Bengal, India,	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata-700017, West Bengal, India. ECR/359/Inst/WB/2013/RR-16	Dr. Kheya Ghosh Uttam

4	JSS Hospital, Mahatma Gandhi Road, Mysuru-570004, Karnataka, India.	Institutional Ethics Committee, 3rdfloor, JSS Medical College, S.S. Nagar, Mysuru-570015, Karnataka, India ECR/387/Inst/KA/2013/RR-16	Dr. M. D. Ravi,
5	KLE's Dr. Prabhakar Kore Hospital Research Center, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590019, Karnataka, India.	Institutional Ethics Committee, JNMC, Campus, Nehru Nagar, Belagavi-590010, Karanataka, India ECR/211/Inst/KA/2013/RR-16	Dr. N. S. Mahantshetti
6	Sri Ramachandra Hospital, No.1, Ramachandra Nagar, Porur, Chennai-600116 Tamil Nadu, India.	Institutional Ethics Committee, Sri Ramachandra Institute of Higher Education & Research (DU), No.1, Ramachandra Nagar, Porur, Chennai-600116, Tamil Nadu, India ECR/203/Inst/TN/2013/RR-16	Dr. Padmasani Venkat Ramanan
7	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- 110062, India ECR/48/Inst/DL/2013/RR-19	Dr. Rekha Harish
8	Manipal Academy of Higher Education, Department of Community Medicine, Kasturba Medical College Located at Dr TMP Pai Hospital, Udipi-576101 and Karkala-574104, Karnataka,	Manipal Academy of Higher Education Ethics Committee, Mezzanine floor, KMC Old Library Building, Madhava Nagar, Manipal-576104, Karnataka, India ECR/191/Inst/KL/2013/RR-16	Dr. Veena Kamath

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

- I. The clinical trial should be conducted as per approved protocol titled "An Open label, Randomized, Active -controlled, Multi-centric Phase-II/III Study in Indian Toddlers and Infants to Assess the Immunogenicity and Safety of SIPL HEXASIL™ (DTwP-HepB-IPV-Hib) Vaccine in Comparison with SIPL Pentavac (DTwP-HepB-Hib) + Poliovac (IPV) Vaccines, Administered as Separate Injections." vide protocol number: SII-wHEXA/IN-02, Version No.: 1.0, Dated 02-May-2019.
- II. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 14-NOV-2019

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