

File No: BIO/CT/20/000001
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 Cadila Healthcare Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213 Telephone No.: 7926868100 FAX: 7926862362 E-mail: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per protocol no.19-07, version 1.0, dated 20/05/2020 in the below mentioned clinical trial sites.

CT No.: CT- 12/2020

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: 10-JUN-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 and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Liquid	
Composition:	Each dose of 0.5 ml contains	
	Name of active ingredient	Quantity
	Diphtheria Toxoid	≤ 4.5 Lf (NLT 2 IU)
	Tetanus Toxoid	≥7.5 Lf (NLT 20 IU)
	Name of Inactive ingredients	Quantity
	Aluminium [Al ³⁺] as AlPO ₄ gel:	NMT 1.25 mg
	2-Phenoxy Ethanol:	2.5 mg
Indications:	For active immunization of children, adolescents and adults from 10 to 60 years of age.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Department of Pediatrics, Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Baazar Ghat, Lakdikapool, Hyderabad-500004, Telangana	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad – 500095, Telangana ECR/300/Inst/AP/2013/RR-19	Dr. N. Ravi Kumar
2	Pt. B. D. Sharma Post Graduate Institute of Medical Sciences, Rohtak-124001, Haryana	Institutional Ethics Committee, Pt. B. D. Sharma Post Graduate Institute of Medical Sciences, Directorate Office, Rohtak124001, Haryana ECR/293/Inst/HR/2013/RR-19	Dr. Savita Verma
3	Department of Community Medicine, Institute of Medical Sciences (IMS) & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneswar – 751003, Odisha	Institutional Ethics Committee, IMS & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneswar – 751003, Odisha ECR/627/Inst/OR/2014/RR-17	Dr. E. Venkata Rao
4	Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata – 700 017, West Bengal	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata – 700 017, West Bengal ECR/359/Inst/ WB/2013/RR-19	Dr. Monjori Mitra
5	Department of Medicine, Government Medical College & Hospital, Medical College Square, Hanuman Nagar, Nagpur-440003, Maharashtra	Institutional Ethics Committee, Department of Pharmacology, Government Medical College, Nagpur – 440003, Maharashtra ECR/43/Inst/MH/2013/RR-19	Dr. Dipti Chand
6	Department of Pediatrics, Bharati Vidyapeeth (Deemed to be	Institutional Ethics Committee, Bharati Vidyapeeth Deemed	Dr. Neeta Hanumante

	University) Medical College & Hospital, Katraj- Dhankawadi, Pune-Satara Road, Pune - 411043, Maharashtra	University, 4 th Floor, Bharati Hospital & Research Centre, Katraj - Dhankawadi, Pune-Satara Road, Pune - 411043, Maharashtra ECR/313/Inst/MH/2013/RR-19	
7	Department of Pediatric Medicine, J. K. Lone Hospital, S.M.S. Medical College & Associated Hospitals, J.L.N. Marg, Jaipur - 302004, Rajasthan	Ethics Committee, S.M.S. Medical College & Attached Hospitals, Jaipur at first floor, Dhanvantri OPD Block, S.M.S. Hospital, J.L.N. Marg, Jaipur - 302004, Rajasthan ECR/26/Inst/RJ/2013/RR-19	Dr. Priyanshu Mathur
8	Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur208002, Uttar Pradesh	Institutional Ethics Committee, Prakhar Hospital, Arya Nagar, Kanpur-208002, Uttar Pradesh ECR/1017/Inst/UP/2017	Dr. Jitendra Singh Kushwaha
9	Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi (Belgaum) - 590002, Karnataka	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers, Belagavi - 590002, Karnataka ECR/1242/Inst/KA/2019	Dr. Amit S. Bhate

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

- I. The clinical trial shall be conducted as per approved protocol titled "A prospective, randomized, two-arm, parallel, single-blind, active-controlled, multicentre, noninferiority clinical study to evaluate the immunogenicity and safety of Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. of M/s Cadila Healthcare Limited compared to Diphtheria and Tetanus vaccine (adsorbed) for adults and adolescents I.P. of M/s Biological E. Limited in healthy subjects" vide protocol no. 19-07, version 1.0 dated 20/05/2020.
- II. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.

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