

File No: BIO/CT/20/000019

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**

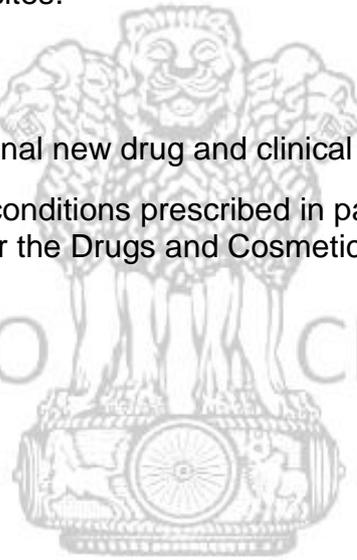
The Central Licencing Authority hereby permits M/s Cadila Healthcare Limited, plot survey no. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213 Telephone No.: 7926868100 FAX: 7926862362 E-mail: sanjaymaheshwari@zyduscadila.com to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: 20-01, Version No.: 01 Date: 26.06.2020** in the below mentioned clinical trial sites.

**CT No.: CT- 19/2020**

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: 11.08.2020



सत्यमेव जयते

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

**Annexure:****Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Typhoid Vi Conjugate Vaccine I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for injection (Intramuscular)	
Composition:	Each single dose of 0.5 ml contains	
	<b>Active ingredient</b>	<b>Quantity</b>
	Purified Vi-capsular polysaccharide of Salmonella typhi	25 mcg
	Conjugated to Tetanus toxoid (Carrier Protein)	16 to 50 µg
	<b>Inactive Ingredients</b>	
	2- Phenoxyethanol	2.50 mg
	Isotonic buffer solution	q.s.
Indications:	For active immunization against Salmonella typhi infection in adults, children and infants.	

**Details of clinical trial sites:**

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	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	All India Institute of Medical Sciences (AIIMS), Patna – 801507, Bihar	Institutional Ethics Committee, All India Institute of Medical Sciences, Patna – 801507, Bihar ECR/1387/Inst/BR/2020)	Dr. Chandramani Singh
3	Institute of Child Health, 11, Dr. Bires Guha Street, Kolkata – 700 017, West Bengal	Institutional Ethics Committee, Institute of Child Health, 11, Dr. Bires Guha Street, Kolkata – 700 017, West Bengal ECR/359/Inst/ WB/2013/RR-19	Dr. Monjori Mitra
4	Institute of Medical Sciences (IMS) & SUM Hospital K 8 Kalinga Nagar, Ghatikia, Bhubaneshwar – 751003, Odisha	Institutional Ethics Committee, Institute of Medical Sciences (IMS) & SUM Hospital K 8 Kalinga Nagar, Ghatikia, Bhubaneshwar – 751003, Odisha ECR/627/Inst/OR/2014/RR-17	Dr Dillip Kumar Dash
5	Department of Pediatrics, Bharati Vidyapeeth (Deemed to be University) Medical College &	Institutional Ethics Committee, Bharati Vidyapeeth Deemed University, 4th Floor, Bharati	Dr. Neeta Hanumante

	Hospital, Katraj- Dhankawadi, Pune- Satara Road, Pune - 411043, Maharashtra	Hospital & Research Centre, Katraj -Dhankawadi, Pune- Satara Road, Pune - 411043, Maharashtra ECR/313/Inst/MH/2013/RR-19)	
6	Kalinga Institute of Medical Sciences (KIMS), Kushabhadra campus (KIIT Campus-5) Patia, Bhubaneswar- 751024, Odisha	Institutional Ethics Committee, Kalinga Institute of Medical Sciences (KIMS), Kushabhadra campus (KIIT Campus-5) Patia, Bhubaneswar- 751024, Odisha ECR/321/Inst/OR/2013/RR-20)	Dr. Nirmal Kumar Mohakud
7	Department of Medicine, S.M.S. Medical College & Associated Hospitals, J.L.N. Marg, Jaipur – 302004, Rajasthan	The 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 – 302 004, Rajasthan ECR/26/Inst/RJ/2013/RR-19)	Dr. Arvind Palawat
8	Department of Pediatric Medicine, J. K. Lon Hospital, S.M.S. Medical College & Associated Hospitals, J.L.N. Marg, Jaipur – 302004, Rajasthan	The 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. Dhan Raj Bagri
9	Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002	Ethics Committee, Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002 ECR/1017/Inst/UP/2017	Dr. Jitendra Singh Kushwaha
10	Vidarbha Institute of Medical Sciences, Mohan Nagar, LIC Square, Kamptee Road, Nagpur - 440001, Maharashtra	Institutional Ethics Committee, Vidarbha Institute of Medical Sciences, Mohan Nagar, LIC Square, Kamptee Road, Nagpur - 440001, Maharashtra ECR/1125/Inst/MH/2018	Dr. Harishankar Gupta
11	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
12	Rana Hospital Pvt. Ltd., Rail Vihar, Medical College Road, Chargawa, Gorakhpur – 273001, Uttar Pradesh	Institutional Ethics Committee, Rana Hospital Pvt. Ltd., Rail Vihar, Medical College Road, Chargawa, Gorakhpur – 273001, Uttar Pradesh ECR/1332/Inst/UP/2020)	Dr. Ajeet Pratap Singh

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, phase IV clinical trial to evaluate the long-term immunogenicity and safety of ZyVac TCV of M/s Cadila Healthcare Limited compared to Typbar TCV of M/s Bharat Biotech International Limited in healthy subjects" vide protocol no. 20-01, version 01 dated 26/06/2020.
- 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.

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