

File No: BIO/CT/21/000130

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.: 21-09 Version No. 00 Date: 20.08.2021** in the below mentioned clinical trial sites.

**CT No.: CT- 37/2021**

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.
4. It may kindly be noted that merely granting permission to conduct Clinical trial with the vaccine does not convey or imply that, based on the Clinical trial data generated with the vaccine, permission to market this vaccine in the country will automatically be granted to you.

Place: New Delhi

Date: 13.10.2021

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:**

No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Era's Lucknow Medical College and Hospital, Sarfarazganj, Lucknow - 22600, Uttar Pradesh	Institutional Ethics Committee, Era's Lucknow Medical College and Hospital, Sarfarazganj, Lucknow- 22600, Uttar Pradesh ECR/717/Inst/UP/2015/RR-18	Dr. Mohammad Moonis Akbar Faridi,
2	Gandhi Medical College & Hospital, Musheerabad, Secunderabad - 500003, Telangana	Institutional Ethics Committee, Gandhi Medical College and Hospital, Musheerabad, Secunderabad-500003, Telangana (ECR/180/Inst/AP/2013/RR-19)	Dr. K. Siva Ram Prasad
3	Yashwantrao Chavan Memorial (YCM) Hospital, Sant Tukaram Nagar, Pimpri, Pimpri-Chinchwad, Pune - 411018, Maharashtra	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune - 411018, Maharashtra (ECR/1236/Inst/MH/2019)	Dr. Deepali Ambike
4	Mahatama Gandhi Medical College and Hospital, RIICO Institutional Area, Tonk Road, Sitapura, Jaipur - 302022, Rajasthan	Institutional Ethics Committee, Mahatama Gandhi Medical College and Hospital, RIICO Institutional Area, Tonk Road, Sitapura, Jaipur - 302022, Rajasthan (ECR/125/Inst/RJ/2013-RR-19)	Dr. Munish Kumar Kakkar
5	Institute of Medical Sciences (IMS) & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneshwar - 751003, Odisha	Institutional Ethics Committee, Institute of Medical Sciences (IMS) & SUM Hospital, Kalinga Nagar, Ghatikia, Bhubaneshwar - 751003, Odisha (ECR/627/Inst/OR/2014/RR-20)	Dr. Dilip Kumar Dash

6	All India Institute of Medical Sciences (AIIMS), Patna - 801507, Bihar	Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), Patna - 801507, Bihar (ECR/1387/Inst/BR/2020)	Dr. Chandramani Sing
7	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
8	Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata - 700017, West Bengal	Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata - 700017, West Bengal (ECR/359/Inst/WB/2013/RR-19)	Dr. Monjori Mitra
9	King George's Medical University, Shahmeena Road, Chowk, Lucknow-226003, Uttar Pradesh	Institutional Ethics Committee, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow-226003, Uttar Pradesh ECR/262/Inst/UP/2013/RR-19	Dr. Nishant Verma
10	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, 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
11	Jawahar Lal Nehru Medical College & Hospital, Kala Bagh, Ajmer - 305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College & Hospital, Kala Bagh, Ajmer - 305001, Rajasthan (ECR/1156/Inst/RJ/2018)	Dr. Jai Prakash Narayan
12	College of Medicine & Sagore Dutta Hospital, 578, B.T. Road, Kamarhati, Kolkata - 700058, West Bengal	Institutional Ethics Committee, College of Medicine & Sagore Dutta Hospital, 578, B.T. Road, Kamarhati, Kolkata - 700058, West Bengal (ECR/1210/Inst/WB/2019)	Dr. Saumyen De
13	Prakhar Hospital Pvt. Ltd., 8/219, Arya Nagar, Kanpur-208002, Uttar Pradesh	Institutional Ethics Committee, Prakhar Hospital, Arya Nagar, Kanpur-208002, Uttar Pradesh (ECR/1017/Inst/UP/2017/RR-21)	Dr. Virendra Nath Tripathi
14	Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargawan, Gorakhpur - 273001, Uttar Pradesh	Institutional Ethics Committee, Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargawan, Gorakhpur - 273001, Uttar Pradesh ECR/1332/Inst/UP/2020	Dr. Vishal Tripathi
15	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector No. 7, Vidhyadhar Nagar, Jaipur - 302039, Rajasthan	Institutional Ethics Committee, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector No. 7, Vidhyadhar Nagar, Jaipur - 302039, Rajasthan (ECR/1222/Inst/RJ/2019)	Dr. Vinay Kumar Gill

16	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. Abhishek Chavan
17	Pulse Multispeciality Hospital, Vishwa Arcade Mumbai Bangalore Highway, Narhe, Ambegaon, Pune - 411041, Maharashtra	Institutional Ethics Committee, Pulse Multispeciality Hospital, Vishwa Arcade Mumbai Bangalore Highway, Narhe, Pune - 411041, Maharashtra (ECR/1339/Inst/MH/2020)	Dr. Prashant Namdev Khandgave
18	Mankar Hospital, Swaroop Housing Society, Plot No 19, Narveer Tanaji Malusare Road, Anandnagar, Pune - 411051, Maharashtra	Institutional Ethics Committee, Pulse Multispeciality Hospital, Vishwa Arcade Mumbai Bangalore Highway, Narhe, Pune - 411041, Maharashtra (ECR/1339/Inst/MH/2020)	Dr. Sanjay Vasant Mankar
19	Shivnath Children Hospital, Amar Complex, Near GIPCL Circle, Chankyapuri Road, New Sama, Vadodara - 390024, Gujarat	Anand Institutional Ethics Committee, Anand Multispeciality Hospital Pvt. Ltd., White House, Opposite Rajasthan Hospital, Shahibaugh, Ahmedabad 380004, Gujarat (ECR/412/Inst/GJ/2013)	Dr. Ravi Modi
20	Aatman Hospital, 5, Anveshan Row House, Opp. Bopal Garn BRTS, Bopal-Ghuma Road, Bopal, Ahmedabad - 380058, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, Bopal-Ghuma Road, Bopal, Ahmedabad - 380058, Gujarat (ECR/1565/Inst/GJ/2021)	Dr. Chintan Patel

In addition to point 4, the permission is subject to following conditions:

- I. The active post-marketing surveillance study shall be conducted as per approved protocol titled " An active post-marketing surveillance study to evaluate the safety and immunogenicity of ZyVac TCV of M/s Cadila Healthcare Limited in healthy subjects" vide protocol no. 21-09, version 00 dated 20.08.2021.
- II. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi

Date: 13.10.2021

(Dr. V. G. Somani)  
 Drugs Controller General (India)  
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