

File No: BIO/CT/25/000009  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Biological Division)

**From:**

The Drugs Controller General, India  
Directorate General of Health Services,

FDA Bhawan Kotla Road,  
New Delhi-110002

**To,**

M/s Zydus Lifesciences Limited,  
Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50,  
Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala,  
Village: Changodar, Taluka - Sanand,  
Dist.: Ahmedabad, Gujarat (India) -382213.

**Subject:** Permission for conducting a clinical trial titled "A prospective, parallel, open-label, two-arm, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Typhoid Vi Conjugate Vaccine I.P. of M/s. Zydus Lifesciences Ltd. in malnourished children as compared to healthy children" Protocol number Protocol no: ZTCV.24.001 Version: 01 Dated: 20 Jan 2025-regarding.

**Reference:** Your Application No. BIO/CT04/FF/2025/47432 dated 21-Jan-2025 on the subject mentioned above.

**Sir,**

Please refer to your application no. BIO/CT04/FF/2025/47432 dated 21-Jan-2025, received by this office on the above subject. Please find enclosed herewith permission to conduct phase IV clinical trial of "Typhoid Vi Conjugate Vaccine I.P." in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

**Yours faithfully,**

**(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)**

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**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 Zydus Lifesciences Limited, Plot Survey No.23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village:Changodar, Tal : Sanand, Dist : Ahmedabad - 382213, State: Gujarat, (India), Telephone No. 91-2717-664600, Fax: 91-2717-664600, E-Mail: sanjaymaheshwari@zyduslife.com to conduct Phase-IV clinical trial of the new drug or investigational new drug as per [Protocol No.: ZTCV.24.001,Version Number: 01 Dated : 20th Jan 2025] in the below mentioned clinical trial sites.

**CT No.: CT- 05/2025**

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:

(Dr. Rajeev Singh Raghuvanshi)  
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:	Typhoid Vi Conjugate Vaccine I.P	
Therapeutic class:	Vaccine	
Dosage form:	Vaccines (Liquid) Injection for Intramuscular route of administration	
Composition:	Each Single dose of 0.5 mL contains:	
	<b>Name of Ingredients</b>	<b>Quantity</b>
	<b>Active Ingredient</b>	
	Purified Vi-capsular polysaccharide of <i>Salmonella typhi</i>	25 mcg
	Conjugated to Tetanus toxoid (Carrier Protein)	16 to 50µg
<b>Inactive ingredient</b>		
2 - Phenoxyethanol (as preservative)	2.50 mg	
Isotonic buffer solution	q.s	
Indication(s):	For active immunization against <i>Salmonella typhi</i> infection in 6 months to 65 years age group.	

### Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Sites	Ethics Committee details	Name of Principal Investigators
1.	V.S. General Hospital, Madalpur Gam, Near Ellisbridge, Paldi, Ahmedabad-380006, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row house, opp. Umiya mata mandir, Bopal-Ghuma Main Road, Bopal, Ahmedabad- 380058, Gujarat Registration No: ECR/1565/Inst/GJ/2021	Dr. Rehan Ansari
2.	Department of Pediatrics, Dhiraj Hospital, SBKS MI & RC, At & Post: Piparia, Taluka: Waghodia, Vadodara-391760, Gujarat, India	Sumandeep Vidyapeeth, Institutional Ethics Committee, At & Post: Piparia, Taluka: Waghodia, Vadodara-391760, Gujarat. Registration No: ECR/152/Inst/GJ/2013/RR-24	Dr Javdekar Bakul Balchandra
3.	Marwari Hospitals, B3, Sati Joymati Road, Athgaon, Guwahati-781008, Assam	ECRC-HEC, Marwari Hospitals, Sati Joymati Road, Athgaon, 781008, Assam. Registration No: ECR/487/Inst/AS/2013/RR-19	Dr Dinesh Agrawal Ramabhai
4.	Hi-Tech Medical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar 751025, Odisha	Institutional Ethics Committee, Hi-Tech Medical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar - 751025, Odisha Registration No: ECR/273/Inst/OR/2013/RR-20	Dr. Lisa Sarangi

5.	Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Lakdikapul, Hyderabad-500004, Telangana	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad- 500059, Telangana Registration No: ECR/300/Inst/AP/2013/RR-24	Dr N Ravi Kumar
6.	Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow - 226010, Uttar Pradesh	Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow - 226010, Uttar Pradesh Registration No: ECR/913/Inst/UP/2017/RR-20	Dr. Neha Thakur Rai
7.	LLR Hospital, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh	Ethics Committee, GSVM Medical College, GSVM Medical College, Swaroop Nagar, Kanpur-208002, Uttar Pradesh Registration No: ECR/680/Inst/UP/2014/RR-20	Dr Yashwant Kumar Rao
8.	Aatman Hospital,5, Anveshan Row House, Opp.Umiya Mata Mandir, Bopal-Ghuma Main Road, Bopal,Ahmedabad-380058, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row house, opp. Umiya mata mandir, Bopal-Ghuma Main Bopal, Gujarat Registration No: ECR/1565/Inst/GJ/2021	Dr. Shreyans Shah

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

- I. The clinical trial should be conducted as per approved protocol titled "A prospective, parallel, open-label, two-arm, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Typhoid Vi Conjugate Vaccine I.P. of M/s. Zydus Lifesciences Ltd. in malnourished children as compared to healthy children". Protocol number: ZTCV.24.001 Version: 01 Date: 20 Jan 2025.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. Firm is required to submit Ethics Committee approval for Phase-IV clinical trial.
- IV. Only CDL, Kasauli certified vaccines already approved for manufacturing & marketing shall be used in the Phase-IV clinical trial in India
- V. Firm shall include the Clinical Trial sites from states of Rajasthan, Bihar and Madhya Pradesh also.

Place: New Delhi

Date:

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licensing Authority