File No: BIO/CT/25/000010
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan Kotla Road,
New Delhi-110002
Dated:

From:

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

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, randomized, parallel, single-blind, two-arm, active controlled, multicentre, age de-escalation, phase II clinical trial to evaluate the immunogenicity and safety of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. as compared to Typhoid Vi Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. in healthy participants." [Protocol No: BTPT.24.001; Version No: 01; Dated 21.01.2025] - regarding.

Reference: Your Application No. BIO/CT04/FF/2025/47464 dated 22-01-2025 on the subject mentioned above.

Sir,

Please refer to your application no. No. BIO/CT04/FF/2025/47464 dated 22-01-2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase II Clinical Trial of "Bivalent Typhoid and Paratyphoid A Conjugate Vaccine" 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,

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.09.12 11:39:43 +05'30'

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

File No: BIO/CT/25/000010
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 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. Telephone No.: 91-2717-664605, FAX: 91-2717-664600, E-Mail: sanjaymaheshwari@zyduslife.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No: BTPT.24.001; Version No: 01; Dated 21.01.2025 in the below mentioned clinical trial sites.

CT No.: CT- 17/2025

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.

RAJEEV SINGH RAGHUVANSHI
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Date: 2025.09.12 11:39:59 +05'30'

Place: New Delhi
Date:

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

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Bivalent Typhoid and Paratyphoid A Conjugate Vaccine</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Vaccines (Liquid), Intramuscular Injection 0.5 mL</td></tr>
<tr><td>Composition:</td><td>Composition:
Each dose of 0.5 ml contains:
<table><tr><th>Ingredients</th><th>Quantity/ dose</th></tr><tr><td>Purified Vi capsular polysaccharide of S.typhi conjugated to 16-50 µg of Tetanus toxoid (Carrier protein)</td><td>25 µg</td></tr><tr><td>Purified OS polysaccharide of S.Paratyphoid A conjugated to16-50 µg of Diphtheria Toxoid (Carrier protein)</td><td>25 µg</td></tr><tr><td>2-Phenoxyethanol</td><td>2.5 mg</td></tr><tr><td>Normal Saline</td><td>q.s. to 0.5mL</td></tr></table></td></tr>
<tr><td>Presentation:</td><td>USP Type 1 glass vial (single dose)</td></tr>
<tr><td>Indication(s):</td><td>For active immunization for prevention of Typhoid Fever and Paratyphoid A Fever.</td></tr>
</table>

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Belagavi Institute of Medical Sciences, Dr B.R. Ambedkar Road, Sadashiv Nagar, Belagavi –590001, Karnataka	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Dr B.R. Ambedkar Road, Sadashiv Nagar, Belagavi – 590001, Karnataka ECR/801/Inst/KA/2016/RR-20	Dr. Jyothi S. Doshetty
2	Dhiraj Hospital, SBKS MI & RC, At& Post: Piparia, Taluka: Waghodia, Vadodara-391760, Gujarat,	Sumandeep Vidyapeeth, Institutional Ethics Committee, At & Post: Piparia, Taluka: Waghodia, Vadodara-391760, Gujarat. ECR/152/Inst/GJ/2013/RR-24	Dr. Javdekar Bakul Balchandra
3	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 Road, Bopal, Ahmedabad-380058, Gujarat ECR/1565/Inst/GJ/2021	Dr. Shreyans Shah

4	Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Lakdikapul, Hyderabad-500004, Telangana.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad-500059, Telangana ECR/300/Inst/AP/2013/RR-24	Dr. N RaviKumar
5	Hi-Tech Medical College &Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar -751025, Odisha.	Institutional Ethics Committee, Hi-TechMedical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar–751025, Odisha ECR/273/Inst/OR/2013/RR-20	Dr. LisaSarangi
6	Vani Vilas Hospital, Bangalore Medical College and Research Institute, K R Road Fort, Bangalore 560002, Karnataka.	Ethics Committee of BMCRI, Bangalore Medical College and Research, Institute, Fort K R RoadBengaluru, Urban Karnataka – 560002. ECR/302/Inst/KA/2013/RR-20	Dr. Shivaprakash S C
7	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. Ambuj Yadav
8	Institute of Medical Science and SUM Hospital, K8, Kalinga Nagar, Ghatikia, Bhubaneswar-751003, Odisha	Institutional Ethics Committee, Institute of Medical Sciences & SUM Hospital, K8, Kalina Nagar, Ghatikia, Bhubaneswar-751003, Odisha ECR/627/Inst/OR/2014/RR-20	Dr ChandanDas

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

1. The proposed clinical trial should be conducted as per protocol titled "A prospective, randomized, parallel, single-blind, two-arm, active- controlled, multicentre, age de-escalation, phase II clinical trial to evaluate the immunogenicity and safety of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. as compared to Typhoid Vi Conjugate Vaccine of M/s Zydus Lifesciences Ltd. in healthy participants" vide protocol no. BTPT.24.001; Version No.01; Dated: 21 Jan 2025.
2. The firm has to submit the Bioanalytical Method validation for the ELISA assay for assessment of anti-LPS antibodies and Serum Bactericidal Assay (SBA) for assessment of antibodies against paratyphoid A antigen before analysis of clinical sample.
3. A data safety monitoring board (DSMB) will be constituted to monitor data on an on-going basis to ensure the continuing safety of the participants enrolled in this study and for inclusion of sequentially lower age cohorts in the study (age de-escalation).

4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have on-going stability programme to as certain that the available long-term stability data cover the entire duration of clinical trial.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date: