

File No: BIO/CT/23/000011
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 Licensing Authority hereby permits M/s Zydus Lifesciences Limited , Zydus Corporate Park, Scheme No. 63 Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway Ahmedabad (India) - 382481 Telephone No.: 79-71800000 FAX: 79-48041500 E-Mail: SANJAYMAHESHWARI@ZYDUSLIFE.COM, to conduct clinical trial of the new drug or investigational new drug as per Protocol No: 23-01 Version No. 02, Dated 14/08/2023 in the below mentioned clinical trial sites.

CT No.: CT-12 /2023

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:

**RAJEEV
SINGH**

RAGHUVANSHI
(Dr. Rajeev Singh, Raghuvanshi)
Drug Controller General (India)
Central Licensing Authority
Stamp

Digitally signed by RAJEEV SINGH
RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS
STANDARD CONTROL ORGANIZATION,
ou=RAJEEV SINGH RAGHUVANSHI,
2.5.4.20=80c62f6a23e4eafbe8a239774c
deb03c2769041015a06564fe67f54b765
db1cb, postalCode=600034, st=TAMIL
NADU,
serialNumber=57556472000000000000
B0C50250C0E93CA12AFA120E0449,
5201124A19013, cn=RAJEEV SINGH
RAGHUVANSHI
Date: 2023.11.23 11:03:39 +05'30'

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 Intramuscular injection	
Composition:	Each Single dose of 0.5 ml vaccine contains:	
	Ingredients	Quantity
	Purified Vi-capsular polysaccharide of <i>S. typhi</i> .	25 mcg
	Conjugated to Tetanus toxoid (Carrier Protein)	16 to 50 µg
	2 - Phenoxyethanol (as preservative)	2.50 mg
	Isotonic buffer solution	q.s
Indications:	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 Site	Ethics Committee details	Name of Principal Investigator
1	Aatman Hospital, 5, Anveshan row house Bopal - Ghuma Road, BRTS, opp. Bopal road, Bopal Ahmedabad Gujarat - 380058	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 B Patel
2	Maharaja Agrasen Super Specialty Hospital, Central spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar Jaipur Rajasthan - 302039.	Institutional Ethics Committee, Maharaja Agrasen Hospital Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur - 302039, Rajasthan [ECR/1222/Inst/RJ/2019].	Dr Prabhat Kumar Sharma
3	Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pimpri- Chinchwad Pune Maharashtra - 411018	Institutional Ethics Committee Yashwantrao Chavan Memorial Hospital, Pimpri. Sant Tukaram Nagar, Near D.Y.Patil Medical College Vallabh Nagar, Near Fire Brigade Station, Pimpri Pune Maharashtra - 411018 India . [ECR/1236/Inst/MH/2019]	Dr Deepali Ambike
4	KLES Dr Prabhakar Kore Hospital and Medical Research Center, NH Service Road,	Institutional Ethics Committee, KLE University, KLE Dr.PK Hospital and MRC, Nehru	Dr.Jayaprakash Appajigol

	Basava Circle, Chikodi, Nehru Nagar, Belagavi Belagavi Karnataka -590010	Nagar Belagavi Belagavi (Belgaum), Karnataka -590010 India [ECR/211/Inst/KA/2013/RR-19]	
5	All India Institute of Medical Sciences, Patna – Aurangabad Rd, Phulwari Sharif Patna Bihar- 801507	Institutional Ethics Committee - All India Institute Of Medical Sciences, Patna, Phulwarisharif Patna Bihar - 801507 India [ECR/1387/Inst/BR/2020]	Dr Chandramani Singh
6	Hi-Tech Medical College and Hospital, Hi-Tech Hospital Road, Pandra, Rasulgarh, Bhubaneswar Orissa - 751025	Institutional Ethics Committee Hi Tech Medical College and Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar, Khordha, Orissa – 751025 [ECR/273/Inst/OR/2013/RR-20]	Dr Lisa Sarangi

In addition to point 3, the permission is subject to following condition(s):

1. The Phase IV clinical trial should be conducted as per title “A prospective, randomized, parallel, two-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid Vi conjugate vaccine with Yellow fever vaccine administered to healthy subjects”. [Study Project No. 23-01, Version No. 02, Dated 14/08/2023]
2. DSMB is required to be constituted to review the safety data of phase IV clinical trial.
3. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures.
4. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi

Date:

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Central Licencing Authority
Stamp

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD
CONTROL ORGANIZATION, ou=RAJEEV SINGH
RAGHUVANSHI,
2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c2
769041015a06564e97f54b765d01cb,
email=rajeev.singh@cdco.gov.in,
serialNumber=D0E1FE73CFA1227A1A126A94FA5701124A19013,
cn=Dr. Rajeev Singh Raghuvanshi