File No: BIO/CT/21/000062

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.: 21-03 version no. 01 dated 17.08.2021** in the below mentioned clinical trial sites.

CT No.: CT- 32/2021

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: 08.09.2021

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2021.09.08 18:25:36 +05'30'

(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	
	Active ingredient	**Quantity**
	Purified Vi-capsular polysaccharide of Salmonella typhi	25 mcg
	Conjugated to Tetanus toxoid (Carrier Protein)	16 to 50 µg
	Inactive Ingredients	
	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	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 Yes (ECR/1156/Inst/RJ/2018)	Dr. Veer Bahadur Singh
2	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-20	Dr Chandan Dash
3	Hi-Tech Medical College & Hospital, Health Park, Pandra, Rasulgarh, Bhubaneswar – 751025, Odisha	Institutional Ethics Committee, Hi-Tech Medical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar –751025, Odisha ECR/273/Inst/OR/2013/RR-20	Dr. Lisa Sarangi
4	Maharaja Agrasen Hospital Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector 7, Vidyadhar Nagar, Jaipur - 302039, Rajasthan	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. Deepak Sharma
5	Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Veer Chambers,	Institutional Ethics Committee, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road, Opp. Civil	Dr. Amit Bhate

	Belagavi (Belgaum) – 590002, Karnataka	Hospital, Veer Chambers, Belagavi – 590002, Karnataka ECR/1242/Inst/KA/2019	
6	Aatman Hospital, 5, Anveshan Row House, Opp Umiya Mata Mandir, 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 Phase III clinical trial shall be conducted as per approved protocol titled " A prospective, randomized, two-arm, parallel, active-controlled, multicentre, non-inferiority, phase III clinical trial to evaluate the 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 adults aged 45 to 65 years" vide protocol no. 21-03, version 01 dated 17.08.2021.
II. Only CDL, Kasauli certified batches shall be used in the clinical trial.
III. DSMB shall be constituted for the evaluation of safety data of the clinical trial.
IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.

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Date: 2021.09.08 18:25:48 +05'30'

Place: New Delhi
Date: 08.09.2021

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