

File No: BIO/CT/20/000135
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 Mr. Syed S Ahmed of M/s Techinvention Lifecare Pvt Ltd, 702, Samarpan Complex, New Link Road Chakala, Andheri East, Mumbai Mumbai (India) - 400099 Telephone No.: 02240052123 FAX: 02240052123 E-Mail: SYED@TECHINVENTION.BIZ to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: EPV/TLC/P-III/2020 Version No. 2.0 Protocol Date 07-MAR-2021 in the below mentioned clinical trial sites.

CT No.: CT-13/2021

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.

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Place: New Delhi
Date: 20-MAY-2021

(Dr. V. G. Somani)
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:	Oral Cholera Vaccine (Inactivated)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid suspension for route of administration	
Composition:	Each dose of 1.5 ml vaccine contains:	
	Name of Active ingredient	Quantity
	V. cholerae O1 Inaba Cairo 48 classical biotype, Heat inactivated	300 L.E.U*
	V. cholerae O1 Inaba Phil 6973 El Tor biotype, Formalin inactivated	600 L.E.U*
	V. cholerae O1 Ogawa Cairo 50 classical biotype, Formalin inactivated	300 L.E.U*
	V. cholerae O1 Ogawa Cairo 50 classical biotype, Heat inactivated	300 L.E.U*
	V. cholerae O139 4260B, Formalin inactivated	600 L.E.U*
	Name of Inactive ingredients	Quantity
	Sodium phosphate dibasic dihydrate	4.68 mg
	Sodium phosphate monobasic dihydrate	0.97 mg
	Sodium chloride	12.75 mg
	Thimerosal	0.15 mg
	Water for injection	q.s to 1.5 mL
	*L.E.U: Lipopolysaccharide ELISA Units.	
Indications:	For Prevention of cholera caused by Vibrio Cholerae	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, New Delhi-110029 India	The Chairman Institute Ethics Committee All India Institute of Medical Sciences Old OT Block, Room No. 102, AIIMS Hospital Ansari Nagar, South Delhi Delhi - 110029 India ECR/538/Inst/DL/2014/RR-20	Dr. Sanjay K Rai
2	All India Institute of Medical Sciences, Phulwarisharif Patna Bihar -801507 India.	IEC-AIIMS-P All India Institute Of Medical Sciences, Patna Phulwarisharif Patna Bihar - 801507 India ECR/1387/Inst/BR/2020	Dr.Chandramani Singh
3	Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road Opp Civil Hospital Belagavi (Belgaum) Karnataka - 590002 India.	Institutional Ethics Committee Jeevan Rekha Hospital Dr. B.R. Ambedkar Road Opp Civil Hospital Belagavi Belagavi (Belgaum) Karnataka - 590002 India ECR/1242/Inst/KA/2019	Dr. Abhishek T. Chavan

4	Prakhar hospital Pvt. Ltd. 8/219 Arya Nagar Kanpur 208002 Uttar Pradesh, India.	Ethics Committee, Prakhar hospital Pvt. Ltd. 8/219 Arya Nagar Kanpur 208002 Uttar Pradesh, India, ECR/1017/Inst/UP/2017	Dr. Amit Chawla
5	Aartham Multi Super Speciality Hospital, Opp. Polytechnic, NR. Panjarapole cross road, Ambawadi, Ahmedabad. 380006	Aartham Ethics Committee Aartham Hospitals LLP Opp. Polytechnic, Near Panjarapole Cross Road, Ambawadi, Ahmedabad Gujarat - 380015 India ECR/1520/Inst/GJ/2021	Dr. JinenMukeshbhai Shah
6	Pt. B.D. Sharma post graduate institute of medical sciences, Director office Rohtak 124001.	Institutional Ethics Committee, Pt. B.D. sharma post graduate institute of medical sciences, Director office Rohtak 124001 ECR/293/Inst/HR/2013/RR-2016	Dr. Vinod Kumar Chayal
7	Niloufer Hospital, Red Hills, Lakdikapool, Hyderabad-500004, Telangana	Institutional Ethics Committee Osmania Medical College Osmania Medical College, Koti, Hyderabad, 500095 ECR/300/Inst/AP/2013/RR-19	Dr. N Ravi Kumar
8	Government Institute of Medical Sciences, Greater Noida, Gautam Budh Nagar, UP-201310,	Institutional Ethics Committee Government Institute of Medical Sciences Kasna, Greater Noida, Gautam Buddha Nagar Uttar Pradesh - 201310 India ECR/1224/Inst/UP/RR-2019	Dr. Rambha Pathak

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 Phase III, open label, multicenter, parallel group, randomized Clinical Study to compare the Immunogenicity and Safety of Euvichol-Plus vaccine with Oral Cholera Vaccine ShancholTM in healthy adults and children above age of one year" [Protocol: EPV/TLC/P-III/2020, Version No.:2.0, Date: 7th March 2021]".
- II. Firm is required to obtain permission in Form CT-17 for import "Oral Cholera vaccine" for use in the said clinical trial.
- III. Firm is required to constitute a DSMB to review the safety data.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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(Dr. V. G. Somani)

Drugs Controller General (India)
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Place: New Delhi
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