File No: BIO/CT/21/000133

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 Bharat Biotech International Limited, Genome Valley, Shameerpet (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:dra@bharatbiotech.com, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: BBIL/BBV-Hillchol®(BBV131)/2021 Version No: 2.0; Date: 21-09-2021** in the below mentioned clinical trial sites.

CT No.: CT- 43/2021

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.

VENUGOPAL G SOMANI

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Date: 2021.12.31 15:18:04 +05'30'

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

Stamp

Place: New Delhi
Date: 31-DEC-2021

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Cholera Vaccine (Inactivated, Oral), I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Oral Liquid Vaccine	
Composition:	Each 2ml respule contains 1.5 ml Single Dose of Vaccine:	
	Ingredients	**Quantity**
	V.Cholerae (O1 EI Tor Hikojima Serotype recombinant strain) formaldehyde Inactivated Whole Cell	≥ 900 mcg of LPS
	Phosphate Buffered Saline	q.s to 1.5 ml
Indications:	For active immunization against Diarrohoeal Infection	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Redkar Hospital and Research center, Oxelbag, Dhargal, Goa 403513,India	Institutional Ethics Committee, Redkar Hospital and Research center, Oxelbag, Dhargal, Goa 403513,India [ECR/902/Inst/GA/2018]	Dr. Sagar Vivek Redkar
2	King George Hospital, Vishakapatnam	Institutional Ethics Committee, King George Hospital, Vishakapatnam [ECR/627/Inst/OR/2014/RR-20]	Dr. R Vasudev
3	Pt. B.D Sharma , Post Graduate Institute of Medical Sciences , University of Health Sciences , Rohtak, Haryana, India- 124001	Institutional Ethics Committee, PGIMS UHS, Pt. B.D Sharma , Post Graduate Institute of Medical Sciences , University of Health Sciences , Rohtak, Haryana, India-124001 [ECR/293/Inst/HR/2013/RR-19]	Dr.Savita.Verma
4	Indian Council of Medical Research – National Institute of Cholera and Enteric Diseases , P-33, CIT Rd, Scheme-XM Beliaghata, Kolkata, West Bengal 700010	Institutional Ethics Committee of Indian Council of Medical Research – National Institute of Cholera and Enteric Diseases , P-33, CIT Rd, Scheme-XM Beliaghata, Kolkata, West Bengal 700010 [ECR/416/Inst/WB/2013/RR-20]	Dr. Suman Kanungo
5	Institute of Medical sciences & SUM Hospital, K8, Kalinga Nagar, Ghatikia, Bhubaneshwar - 751003, Odisha	Institutional Ethics Committee, IMS & SUM Hospital, K8, Kalinga Nagar, Ghatikia, Bhubaneshwar 751003, Odisha ECR/627/Inst/OR/2014/RR-20]	Dr. E. Venkata Rao

In addition to point 4, the permission is subject to following condition(s):

I. The Phase III clinical trial should be conducted as per title “Protocol Title: A Phase III randomized, modified double-blind, multi-centric, comparative study, to evaluate the non-inferiority of immunogenicity and safety of single strain oral cholera vaccine Hillchol® to the comparator vaccine Shanchol™ along with lot-to-lot consistency of Hillchol®.” vide Protocol No: BBIL/BBV-Hillchol®(BBV131)/2021 Version No: 2.0; Date: 21-Sept-2021.
II. The firm is required to constitute a DSMB to review the safety data.
III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.
IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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Date: 2021.12.31 15:18:13 +05'30'

Place: New Delhi
Date: 31-DEC-.2021

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