File No: BIO/CT/21/000074
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 Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail:varma.bhupathiraju@biologicale.com to conduct clinical trial of the new drug or investigational new drug as per pprotocol no. BECT068/LPV-PIV-Bridging/CTP-01, Version no. 1.0 dated 26.03.2021 in the below mentioned clinical trial sites.

CT No.: CT- 36/2021

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 GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.10.12 16:45:27 +05'30'

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

Date: 12-Oct-2021
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug	Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (r-DNA) and Haemophilus influenza type b Conjugate Vaccine (Adsorbed)	
Therapeutic class	Vaccine	
Dosage form	Suspension for Intramuscular Injection.	
Composition	Each dose of 0.5 mL contains:	
	Name of Active ingredient	**Quantity**
	Diphtheria Toxoid	25 Lf (≥ 30 IU)
	Tetanus Toxoid	5.5 Lf (≥ 60 IU)
	B. Pertussis (Whole Cell)	16 IOU (≥ 4 IU)
	r-HBsAg	12.5μg
	Purified Capsular Polysaccharide of Hib (PRP) covalently linked to 20 to 36.7μg of tetanus toxoid	11μg
	Name of Inactive ingredients	
	Al+++ (as AlPO4)	≤ 1.25 mg
	Thiomersal	0.01% w/v
Indications	For active immunization against diphtheria, tetanus, pertussis (whooping cough), Hepatitis B and hib disease in infants from 6 weeks of age.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	IMS & SUM Hos pi tal , K-8, Gha tikia, Bhubaneswar, 751003	Institute of Medical Sciences & SUM Hospital, K8 Lane 1, Kalinganagar, Bhubaneswar - 751003, Odisha, India [ECR/627/Inst/OR/2014/RR-20]	Dr. Smaraki Mohanty
2.	Mysore Medical College and Research Institute, Irwin Road, Mysore-570001, Karnataka, India	Institutional Ethics Committee-MMC and RI and Associated Hospital, Mysore Medical College and Research Institute Mysore Medical College and Research Institute Irwin Road Mysuru (Mysore) Karnataka-570001India.[ECR/134/Inst/KA/2013/RR-19]	Dr. S. Prashanth
3.	Government Medical College and Hospital, Ajni, Nagpur-440003, Maharashtra, India.	Institutional Ethics Committee, GMC, Nagpur Government Medical College and Hospital, Nagpur Government Medical College, Medical Square Hanuman Nagar Nagpur Nagpur Nagpur Maharashtra-440003, India [ECR/43/Inst/MH/2013/RR-19]	Dr. Uday Wasudevrao Narlawar
4.	Jawahar Lal Nehru Medical College,Ajmer-305001, Rajasthan,India.	Institutional Ethics Committee Jawahar Lal Nehru Medical College Kala Bagh Ajmer Ajmer Ajmer Rajasthan - 305001, India [ECR/1156/Inst/RJ/2018]	Dr. Jai Prakash Narayan
5.	Lata Mangeshkar Multi Speciality Hospital, YMCA	Institutional Ethics Committee, NKP Salve Institute of Medical Sciences Digdoh Hills	Dr. Anju J.K Mehrotra

	Complex, Maharajbagh Road, Sitabuldi, Nagpur-440012, Maharashtra, India	Hingna road Nagpur Nagpur Maharashtra - 440019 India [ECR/88/Inst/MH/2013/RR-19]	
6.	Belagavi Institute of Medical Sciences,Dr B R Ambedkar Road Belagavi-590010Karnataka, India.	Institutional Ethics Committee BIMS Belagavi Institute Of Medical Sciences, Belagavi Dr B R Ambedkar Road Belgaum Belgaum Belagavi(Belgaum) Karnataka - 590001India. [EC/RENEW/INST/2020/8844]	Dr Shailesh Patil
7.	National Institute of Medical Sciences and Research (NIMS),Shobha Nagar, Jaipur-Delhi HighwayNH-11C Jaipur - 303121 Rajasthan, India.	Institute of Ethichs Committee, National Institute of Medical Sciences and Research (NIMS),Shobha Nagar, Jaipur-Delhi Highway NH-11C Jaipur - 303121Rajasthan [ECR/88/Inst/RJ/2014/RR-17]	Dr. Yograj Khinchi

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

I. The Phase IV clinical trial should be conducted as per approved protocol titled "A prospective open label comparative phase-IV bridging study to assess the equivalence of the revised DTwP-rHepB-HIB vaccine formulation with that of the currently licensed DTwP-rHepB-HIB formulation in 6-8 weeks old infants" vide protocol no. BECT068/LPV-PIV-Bridging/CTP-01, Version no. 1.0 dated 26.03.2021.

II. The firm is required submit following data/documents:

a. Constitute a DSMB to review the safety data of Phase IV clinical trial.
b. Copy of the Investigators Brochure for proposed Phase IV Clinical trial.
c. Copy of the Ethics Committee approval.
a. Copy of the Insurance Certificate shall be provided to Ethics Committee before the initiation of trial.
b. The details of central clinical trial laboratory where the blood samples testing will be carried out.

III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.

IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.10.12 16:45:42 +05'30'

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

Date: 12-Oct-2021
Place: New Delhi

Stamp

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA