File No: BIO/CT/21/000033

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. Mohammed Shafiqur Rahman of M/s Ra (biologicals) Panacea Biotec Ltd., A-27, B-1 Extension Mohan Cooperative Industrial Estate, Mathura Road New Delhi (India) - 110044 Telephone No.: null FAX: null E-Mail : shafiqurrahman@panaceabiotec.com to conduct clinical trial of the new drug or investigational new drug as per pprotocol no. PBL/20/01/PNCV, Version Number: 03, Dated 31-July-2021 in the below mentioned clinical trial sites.

CT No.: CT- 39/2021

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

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

Date: 22-Oct-2021
Place: New Delhi

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (11-valent)	
Therapeutic class:	Vaccine	
Dosage form:	suspension for Injection by Intramuscular route	
Composition:	Each 0.5mL of Vaccine contains:	
	Ingredients	**Quantity**
	Purified polysaccharide *S.pneumoniae* serotype 1*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 5*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 6A*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 6B*	4.4 µg
	Purified polysaccharide *S.pneumoniae* serotype 7F*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 9V*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 14*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 18C*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 19A*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 19F*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 23F*	2.2 µg
	Inactive Ingredients:	
	Aluminum content (Al3+) (as Aluminum Phosphate Gel)	NMT 1.25 mg
	2-Phenoxyethanol	3.0 mg
	Polysorbate 20	≥0.02% w/v
	Succinate buffer saline	q.s. to 0.5ml
	*Conjugated to CRM_{197} carrier protein	
Indications:	For protection against invasive pneumococcal disease due to Streptococcus pneumoniae.	

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, Aurangabad Rd, Phulwari Sharif, Patna, Bihar 801507	IEC-AIIMS-P, All India Institute of Medical Sciences, Aurangabad Rd, Phulwari Sharif, Patna, Bihar 801507. [ECR/1387/Inst/BR/2020]	Dr Chandramani Singh
2	Dr N. S. Mahantshetti, KLES Dr Prabhakar Kore Hospital & MRC, Nehru Nagar , Belagavi-	Institutional Ethics Committee , Dr N. S. Mahantshetti, KLES Dr Prabhakar Kore Hospital & MRC,	Dr N. S. Mahantshetti

	590010	Nehru Nagar , Belagavi-590010 [ECR/211/Inst/KA/2013/RR-19].	
3	S. N. Medical College, Moti Katra, Mantola, Agra, UP-202003	Institutional Ethics Committee , S N Medical College, Moti Katra, Mantola, Agra, UP-202003 [ECR/1409/Inst/UP/2020]	Dr. Ram Kshitij Sharma
4	Rana Hospital Pvt Ltd Rail Vihar Medical College Road, Chargawa, Gorakhpur-273001	Institutional Ethics Committee Rana Hospital Pvt Ltd Rail Vihar Medical College Road, Chargawa, Gorakhpur-273001 [ECR/1332/Inst/UP/2020]	Dr Vishal Tripathi
5	7-Orange Hospital, Pawana Nagar, Next to Jain School, Near Chapekar Chowk, Chinchwad, Pune- 411033, Maharashtra, India.	Saikrupa Hospital Institutional Ethics Committee Saikrupa Hospital Renuka Corner Tapkir Chowk, Thergaon Pune Pune Maharashtra – 411033. [ECR/1350/Inst/MH/2020]	Dr. Suhas Sodal
6	Niloufer Hospital Redhills, Lakdikapool, Hyderabad, Telangana-500004	Institutional Ethics Committee Osmania Medical College Osmania Medical College, Koti, Hyderabad,500095 [ECR/300/Inst/AP/2013/RR-19]	Dr N. Ravi Kumar
7	Institute of Medical Sciences (IMS) & SUM Hospital, K8, Kalinga,Ghatikia, Bhubaneswar-751003,Odisha	Institutional Ethics Committee , Institute of Medical Sciences (IMS) & SUM Hospital ,K8,Kalinga, GhatikiaBhubaneswar-751003,Odisha [ECR/627/Inst/OR/2014/RR-20].	Dr Dillip Kumar Das
8	King George Hospital, Maharanipeta, Visakhapatnam - 530002, AP	Institutional Ethics Committee, King George Hospital, Maharanipeta, Visakhapatnam - 530002, AP [ECR/197/Inst/KGH/2013/RR-20]	Dr. B. Ramesh Kumar

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

I. The Phase I clinical trial should be conducted as per protocol titled " A Randomized, Open label, Multicenter, Phase II/III study to assess and compare the immunogenicity and safety of NUCOVAC®-11 {Pneumococcal Polysaccharide conjugate vaccine (Adsorbed), 11 valent}of Panacea Biotec Ltd. with PREVENAR13®of Pfizer Inc.in healthy infants (3+1immunization schedule) [Protocol no: PBL/20/01/PNCV, Version Number: 03, Dated 31-July-2021].

II. The firm is required to comply & submit following data/documents:
   a. The firm shall use batches manufactured in Form CT-11 for clinical trial purpose in the proposed trial.
   b. Copy of Form 29 license for manufacturing of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed), 11-valent.
   c. Process validation protocol and reports of Drug product & Drug substances (at least 3 batches) of Monovalent Pneumococcal Polysaccharide conjugated bulks (Drug Substances) of 11 serotypes before initiation of Phase-III Clinical trial.
   d. Analytical method validation data of the each polysaccharides, CRM 197 & monovalent bulk conjugate of all serotypes (at least 3 batches) before proceeding to Phase III Clinical trial.
   e. Consistency and analysis of at least 3 batches of Pneumococcal Polysaccharide conjugate vaccine (Adsorbed), 11-valent and Purified Pneumococcal Polysaccharide, Purified Protein

CRM197 & Monovalent conjugated bulk of Pneumococcal Polysaccharides of 11 different serotypes with CRM 197.

f. The final specification of Drug product & Drug substances of Pneumococcal Polysaccharide conjugate vaccine (Adsorbed), 11-valent before proceeding to Phase II/III CT.
g. Real time & accelerated stability data of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed), 11-valent before proceeding to Phase II/III Clinical trial and to ensure the stability of vaccine during the conduct of the trial.
h. To mention the amount of carrier protein per single human dose in the composition as well as in the draft label.
i. Certificate of analysis of (CoA) of two more batches of Pneumococcal Polysaccharide conjugate vaccine (Adsorbed) (11-valent)
j. Clinical trial agreement / financial plan between the sponsor and investigator/institutions with regard to financial support, amount of fees, honorarium, payments.

III. DSMB should be constituted for review of the safety data of the clinical tria
IV. 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.
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)
Central Licencing Authority

Date: 22-Oct-2021
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CENTRAL DRUGS STANDARD CONTROL ORGANISATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA