File No: BIO/CT/21/000159

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 Pfizer Limited, The Capital 1802/1901, Plot No. C-70 G Block Bandra-Kurla Complex Bandra (E) Mumbai City (India) - 400051 Telephone No.: 022-66932176 FAX: 022-26540274 E-Mail: regulatoryindia@pfizer.com to conduct clinical trial of the new drug or investigational new drug as per protocol no. B1851214 Version No. Final Date 15-OCT-2021 in the below mentioned clinical trial sites.

CT No.: CT- 10/2022

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.

Date: 07-Apr-2022
Place: New Delhi

VENUGOPAL G SOMANI

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Date: 2022.04.07 14:30:24 +05'30'

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

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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (13-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 3*	2.2 µg
	Purified polysaccharide *S.pneumoniae* serotype 4*	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 (AlPO4)	0.125 mg
	CRM_{197} carrier protein	32 mcg
	2-Phenoxyethanol**	
	Polysorbate 20	100 mcg
	Succinate buffer (Succinic acid & Sodium Chloride)	295 mcg
	*Conjugated to CRM_{197} carrier protein adsorbed on Aluminium phosphate **for Multidose	
Indications:	For active immunization for the prevention of Pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults of 18 years to 49 years of age	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
01	Nirmal Hospital Pvt. Ltd., Department of Pediatrics, Ring Road, Surat, Gujarat 395002, India	Nirmal Hospital Ethics Committee,Nirmal Hospital Pvt. Ltd., 2/1423-8-6, Sagrampura Ring Road, Near Centre Point, Surat 395002 Gujarat India ECR/390/Inst/GJ/2013/RR-19	Dr Nirmalkumar Ganeshmal Choraria
2	BGS Global Institute of Medical Sciences and Hospital, No. 67, BGS Health & Education City, Uttarahalli Main Road,Kengeri,	Institutional Ethics Committee, Department of Community Medicine, Room No: 01, Second Floor, College Building BGS Global	Dr Balachandra Giriappa

	Bangalore Karnataka 560060, India	Institute of Medical Sciences, 67, BGS Health and Education City Uttarahalli Road, Kengeri, Bangalore South Karnataka, Bengaluru(Banglore) Urban Karnataka – 560060India ECR/1307/Inst/KA/2019	
3	Aakash Healthcare Private Limited Hospital Plot, Road Number 201, Sector-3, Dwarka, New Delhi, Delhi-110075,India	Aakash Healthcare Institutional Ethics Committee Aakash Healthcare Super Specialty Hospital, Hospital Plot, Road No. 201 Sector 3, Dwarka, New Delhi, Dwarka North West Delhi, Delhi - 110075 India ECR/1265/Inst/DL/2019	Dr Akshay Budhraja
4	JawaharLal Nehru Hospital, Kala Bagh, Ajmer, Rajasthan – 305001,India	Institutional Ethics Committee, Jawaharlal Nehru Medical College, Kala Bagh, Ajmer, Rajasthan-305001, India ECR/1156/Inst/RJ/2018	Dr Sanjiv Maheshwari
5	Calcutta School of Tropical Medicine,108, Chittaranjan Avenue, Kolkata, West Bengal-700073, India	Clinical Research Ethics Committee, School of Tropical Medicine, Kolkata, School of Tropical Medicine 108,ChittaRanjan Avenue, Kolkata-700073Kolkata West Bengal- 700073India ECR/194/Inst/WB/2013/RR-20	Dr Santanu Munshi

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

I. The Phase IV clinical trial should be conducted as per protocol titled "A Phase 4, open-label, single-arm, multicenter study to describe the safety of 13-valent Pneumococcal Conjugate vaccine in adults 18 to 49 years of age in India [Protocol no: B1851214 Version No. Final Date 15-OCT-2021].
II. The firm is required to submit duly signed details of the contract entered by the sponsor with the investigator/institutions with regard to financial support, amount of fees, honorarium, payments in kind etc. to be paid to the investigator. In case no contract has yet been entered with any Investigator / Institution, plan for financial support, fees, honorarium, and payments in kind etc. to be paid to the investigator
III. DSMB should be constituted for review of the safety data of the clinical trial
IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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