

File No: BIO/CT/22/000051
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. 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.: B7471010, Final Protocol Amendment -1, 22-DEC-2022** in the below mentioned clinical trial sites.

CT No.: CT- 01/2023

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.

Date: 12-JAN-2023
Place: New Delhi

VENUGOPAL G SOMANI

Drugs Controller General (India)
Central Licensing Authority
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Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	20-valent Pneumococcal Conjugate (20vPnC) Vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Sterile liquid suspension for intramuscular administration	
Composition:	Each dose of 0.5 mL PFS Contains:	
	Pneumococcal polysaccharide for serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33 F .	2.2 µg
	Pneumococcal polysaccharide for serotype 6B	4.4 µg
	Total Protein (CRM ₁₉₇)	~ 51µg
	Aluminum Phosphate	0.125 mg Al
	Sodium Chloride	4.4mg
	Succinic Acid	0.295 mg
	Polysorbate 80	0.1 mg
	Water for injection	q.s. to 0.5ml
Indications:	For active immunization for the prevention of pneumonia and invasive disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Bharati Vidyapeeth (Deemed to Be University) Medical College Hospital & Research Centre, Pune-Satara Road, Dhankawadi, Pune- 411043, Maharashtra, India.	Institutional Ethics Committee, Bharati Vidyapeeth (Deemed to Be University), Bharati Hospital & Research Centre, Pune- Satara Road, Dhankawadi, Pune-411043, Maharashtra, India [ECR/313/Inst/MH/2013/RR-19]	Dr. Sonali Hemant Palkar
2	BGS Global Institute of Medical Sciences and Hospital, No.67, BGS Health and Education City, Uttarahalli Main Road, Kengeri, Bengaluru - 560060, Karnataka, India	Institutional Ethics Committee, Room No. 01, Department of Community Medicine, BGS Global Institute of Medical Sciences and Hospital No.67, BGS Health and Education City, Uttarahalli Main Road, Zenger, Bengaluru -560060, Karnataka, India [ECR/1307/Inst/KA/201]	Dr. Balachandra G
3	Aakash Healthcare Private Limited. Hospital Plot, Road No. 201 Sector 3 Dwarka New Delhi Dwarka North West Delhi Delhi - 110075 India	Institutional Ethics Committee, Aakash Healthcare Super Specialty Hospital Plot, Road No. 201 Sector 3 Dwarka New Delhi Dwarka North West Delhi Delhi - 110075 India [ECR/1265/Inst/DL/201]	Dr. Akshay Budhraja
4	Jawahar Lal Nehru Hospital, Kala Bagh, Ajmer-305001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical	Dr. Sanjiv Maheshwari

		College, Kala Bagh, Ajmer-305001, Rajasthan. [ECR /1156/Inst/RJ/2018/RR-22]	
5	Calcutta School of Tropical Medicine; 108, Chittaranjan Avenue, Kolkata-700073	Clinical Research Ethics Committee, School of Tropical Medicine, Kolkata School of Tropical Medicine 108, Chittaranjan Avenue, Kolkata - 700073 Kolkata West Bengal - 700073 India [ECR/194/Inst/WB/2013/RR-20]	Dr. Santanu Munshi
6	Raja Rajeshwari Medical College and Hospital, No 202, Mysore Road, Bengaluru, Karnataka, 560074, India.	Institutional Ethics Committee, Raja Rajeshwari Medical College and Hospital No.202, Kambipura, Mysore Road, Bengaluru, Karnataka 560074, India [ECR/56/Inst/KA/2013/RR-19]	Dr. Vivek G
7	Navkar Hospital, Opposite Mental Hospital, Karelbaug, Vadodara, Gujarat, India - 390018	Institutional Ethics Committee Maanav Health Foundation A1 Anupam Nagar Behind Rajvee Towers Near Tube Company Old Padra Road Vadodara Vadodara Gujarat -390020 India. [ECR/2/Inst/GJ/2013/RR-19]	Dr. Bhaveshkumar Mohanlal Patel
8	Nirmal Hospital Pvt. Ltd, Department of Pediatrics, Ring Road, Surat - 395002, Gujarat, India.	Ethics Committee, Nirmal Hospital Pvt. Ltd. Ring Road, Surat - 395002, Gujarat, India. [ECR/390/Inst/GJ/2013/RR-19]	Dr. Nirmalkumar Ganeshmal Choraria
9	Oriion Citicare Super Speciality Hospital 5-5-70 New Osmanpura, Opposite Kalash Mangal Karyalaya Aurangabad, Maharashtra, 431005, India	Institutional Ethics Committee, Oriion Citicare Superspeciality Hospital, 5-5-70. Opp. Kalash Mangal Karyalaya, New Osmanpura, Aurangabad, 431005, Maharashtra, India. [ECR/1548/Inst/MH/2021]	Dr. Deshmukh Ashish Shankarao

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

- The Phase III clinical trial should be conducted as per title "A phase 3, single-arm, multicenter trial to describe the safety and immunogenicity of a 20-valent pneumococcal conjugate vaccine in pneumococcal vaccine-naïve adults ≥ 18 years of age in India" vide Protocol no.: B7471010, Final protocol Amendment -1, 22-DEC-2022.
- The firm is required to constitute a DSMB to review the safety data.
- The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures.
- Only CDL, Kasauli certified batches shall be used in the clinical trial.

Date: 12-JAN-2023
Place: New Delhi

VENUGOPAL G SOMANI
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Dr. V. G. Somani
Drugs Controller General (India)
Central Licensing Authority
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FORM CT-17

(See rules 68, 69, 70, 71 and 72)

LICENCE TO IMPORT NEW DRUG FOR THE PURPOSE OF CLINICAL TRIAL OR BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OR FOR EXAMINATION, TEST AND ANALYSIS**License Number: TL/BIO/23/000001**

The Central Licencing Authority hereby grants licence to M/s Pfizer Limited, The Capital 1802/1901 Plot No. C-70 G Block Bandra-Kurla Complex Bandra (E) Mumbai City-400051 Maharashtra to import new drug or investigational new drug for conduct of clinical trial ~~or bioavailability or bioequivalence study, examination, test and analysis~~ as per **Protocol no.: B7471010, Final Protocol Amendment -1, 22-DEC-2022** in the below mentioned clinical trial sites

S. No.	Name of the new drug to be imported	Therapeutic class of new drug	Quantity to be imported
1.	20-valent Pneumococcal Conjugate (20vPnC) Vaccine	Vaccine	544 Pre-filled syringes (1 Pre filled syringe per pack)

- This license is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.
- This license shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
- Details of overseas manufacturer and manufacturing site under this license.

S. No.	Name and address of manufacturer	Name and address of manufacturing site
1	M/s Pfizer Ireland Pharmaceuticals, Grange Castle Business Park Clondalkin, Dublin 22, Clondalkin (Ireland) - Dublin 22, Telephone No.: 35314694000 FAX: 353146940	<ol style="list-style-type: none"> M/s Pfizer Ireland Pharmaceuticals, Grange Castle Business Park Clondalkin, Dublin 22, Clondalkin (Ireland) - Dublin 22, Telephone No.: 35314694000 FAX: 35314694001 M/s Almac Clinical Services Limited, Seagoe Industrial Estate 9, Charlestown Road, Craigavon, Northern Ireland (United Kingdom)-BT63 5PW, Telephone No.:4402838362436, FAX: 4402838363800

- The licensee shall maintain the record imported new drug or investigational new drugs [As per Annexure].

Place: New Delhi
Date: 12-JAN-2023

VENUGOPAL G SOMANI
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Annexure:

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2	BGS Global Institute of Medical Sciences and Hospital, No.67, BGS Health and Education City, Uttarahalli Main Road, Kengeri, Bengaluru - 560060, Karnataka, India	Institutional Ethics Committee, Room No. 01, Department of Community Medicine, BGS Global Institute of Medical Sciences and Hospital No.67, BGS Health and Education City, Uttarahalli Main Road, Zenger, Bengaluru -560060, Karnataka, India [ECR/1307/Inst/KA/201]	Dr. Balachandra G
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5	Calcutta School of Tropical Medicine; 108, Chittaranjan Avenue, Kolkata-700073	Clinical Research Ethics Committee, School of Tropical Medicine, Kolkata School Of Tropical Medicine 108, Chitta Ranjan Avenue, Kolkata - 700073 Kolkata Kolkata West Bengal - 700073 India [ECR/194/Inst/WB/2013/RR-20]	Dr. Santanu Munshi
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7	Navkar Hospital, Opposite Mental Hospital, Karelbaug, Vadodara, Gujarat, India - 390018	Institutional Ethics Committee Maanav Health Foundation A1 Anupam Nagar Behind Rajvee	Dr. Bhaveshkumar Mohanlal Patel

		Towers Near Tube Company Old Padra Road Vadodara Vadodara Gujarat -390020 India. [ECR/2/Inst/GJ/2013/RR-19]	
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Note:

1. The permission is for clinical trial purpose only and not for commercial purpose”.