

File No: BIO/CT/22/000006

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/22/000022

The Central Licensing Authority hereby grants license to Mr. Gautam Chandrakumar Shah of M/s G.C. Chemie Pharmie Ltd., 5C Laxmi Industrial Estate New Link Road Andheri Mumbai (India) – 400053, Telephone No.:02226330365,9619798980, FAX:02226330506, E-Mail: regulatory@gccpl.com to import new drug or investigational new drug for conduct of clinical trial or bioavailability or bioequivalence study as per protocol number: CRN_India/ 0106/2021, Version number: 2.0, Dated 01-03-2022 in the below mentioned clinical trial sites ~~or bioavailability or bioequivalence study centre or for examination, test and analysis at CDL, Kasauli (in the below mentioned clinical trial sites or bioavailability or bioequivalence study centre.~~ [As per Annexure].

Name of the new drug to be imported	Therapeutic class of new drug	Quantity to be imported
Pneumococcal Polysaccharide Conjugate Vaccine I.P. (PCV13-TT) (Adsorbed)	Vaccine	1526 PFS

- 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 Yuxi Walvax Biotechnology Co., Ltd No. 83, South Dongfeng Road, High and New Technology Industrial Development Zone, Yuxi, China, Yuxi (China) -653100, Telephone No.: 86-0877-2077789 FAX: 86-0877-2076918	M/s Yuxi Walvax Biotechnology Co., Ltd No. 83, South Dongfeng Road, High and New Technology Industrial Development Zone, Yuxi, China, Yuxi (China) -653100 Telephone No.: 86-0877-2077789 FAX: 86-0877- 2076918

- The licensee shall maintain the record imported new drug or investigational new drugs [As per Annexure].
- The permission is "Not Commercial purposes".

Place: New Delhi
Date: 07-JULY-2022

**VENUGOPAL G
SOMANI**

Digitally signed by VENUGOPAL G SOMANI
DN: cn=RL, ou=CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION, ou=DRUGS CONTROLLER GENERAL (INDIA),
pseudoym=112046a34e21727baeb255748732c456d249073e55e
95349d55a58748ee3113c, postalCode=110002, st=DELHI,
serialNumber=e97E41aadc0bba41522525fca0705074b4997ed02f
4b5c8d81c7282adeaf5d, cn=VENUGOPAL G SOMANI
Date: 2022.07.07 17:06:47 +05'30'

(Dr. V. G. Somani)
Central Licensing Authority
Stamp

Annexure: 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, Phulwarisharif Patna Bihar -801507, India	Institutional Ethics Committee All India Institute of Medical Sciences, Phulwarisharif Patna Bihar -801507, India [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
2	Niloufer Hospital, Osmania Medical College, Koti, Hyderabad, Telangana -500095, India	Institutional Ethics Committee Niloufer Hospital, Osmania Medical College, Koti, Hyderabad, Telangana -500095, India [ECR/300/Inst/AP/2013/RR-19]	Dr. N Ravi Kumar
3	PGI Rohtak, Department of Community Medicine Room number 405 PGIMS Rohtak Haryana -124001	Institutional Ethics Committee PGI Rohtak, Department of Community Medicine Room number 405 PGIMS Rohtak Haryana -124001 [ECR/293/Inst/HR/2013/RR-19]	Dr Vinod Kumar Chayal
4	Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road Opp Civil Hospital Belagavi (Belgaum), Karnataka - 590002 India	Institutional Ethics Committee Dr. B.R. Ambedkar Road, Opp Civil Hospital Belagavi (Belgaum), Karnataka - 590002 India [ECR/1242/Inst/KA/2019]	Dr. Abhishek T. Chavan
5	Prakhar Hospital Pvt., Ltd., 8/219 Arya nagar, Kanpur 208002 Uttar Pradesh, India	Institutional Ethics Committee Prakhar hospital Pvt. Ltd., 8/219 Arya nagar, Kanpur 208002 Uttar Pradesh, India [ECR/1017/Inst/UP/2017/RR-21]	Dr. V N Tripathi
6	Rana Hospital Pvt., Ltd., Rail Vihar Medical College Road Chargawa Gorakhpur- 273001, Uttar Pradesh, India	Institutional Ethics Committee Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road Chargawa Gorakhpur- 273001, Uttar Pradesh, India	Dr. Vishal Tripathi

FORM CT-06
(See rules 22, 25, 26, 29 and 30)

The Central Licensing Authority hereby permits Mr. Gautam Chandrakumar Shah of M/s G.C. Chemie Pharmie Ltd., 5C Laxmi Industrial Estate New Link Road Andheri Mumbai (India) – 400053, Telephone No.:02226330365,9619798980, FAX:02226330506, E-Mail: regulatory@gccpl.com to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: CRN_India/ 0106/2021, Version number: 2.0, Dated 01-03-2022 in the below mentioned clinical trial sites.

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.

VENUGOPAL G SOMANI
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CONTROL ORGANIZATION, ou=DRUGS
CONTROLLER (Central Drugs Controller
General India), cn=VENUGOPAL G SOMANI
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3113c, postalCode=110002, st=DELHI,
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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 I.P. (PCV13-TT) (Adsorbed)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular injection	
Composition:	Each dose of 0.5 ml contains:	
	Name of Active ingredient	Quantity
	Pneumococcal Polysaccharide Serotype 1	2.6 µg
	Pneumococcal Polysaccharide Serotypes 3	2.5 µg
	Pneumococcal Polysaccharide Serotypes 4	3.0 µg
	Pneumococcal Polysaccharide Serotypes 5	2.5 µg
	Pneumococcal Polysaccharide Serotypes 6A	2.5 µg
	Pneumococcal Polysaccharide Serotypes 6B	6.0 µg
	Pneumococcal Polysaccharide Serotypes 7F	2.85 µg
	Pneumococcal Polysaccharide Serotypes 9V	2.5 µg
	Pneumococcal Polysaccharide Serotypes 14	2.75 µg
	Pneumococcal Polysaccharide Serotypes 18C	3.25 µg
	Pneumococcal Polysaccharide Serotypes 19A	2.6 µg
	Pneumococcal Polysaccharide Serotypes 19F	2.75 µg
	Pneumococcal Polysaccharide Serotypes 23F	3.0 µg
	Name of Inactive ingredient	Quantity
	Aluminum Phosphate	0.5 mg
	Sodium Chloride	4.25mg
	Sodium dihydrogen phosphate	44.35 µg
	Disodium hydrogen phosphate	19.0 µg
	Water for injection	Up to 0.5mL
Indication(s):	Active immunization for the prevention of disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F	

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, Phulwarisharif Patna Bihar -801507, India	Institutional Ethics Committee All India Institute of Medical Sciences, Phulwarisharif Patna Bihar -801507, India [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
2	Niloufer Hospital, Osmania Medical College, Koti, Hyderabad, Telangana -500095, India	Institutional Ethics Committee Niloufer Hospital, Osmania Medical College, Koti, Hyderabad, Telangana -500095, India [ECR/300/Inst/AP/2013/RR-19]	Dr. N Ravi Kumar
3	PGI Rohtak, Department of Community Medicine Room number 405 PGIMS Rohtak Haryana -124001	Institutional Ethics Committee PGI Rohtak, Department of Community Medicine Room number 405 PGIMS Rohtak Haryana -124001	Dr Vinod Kumar Chayal

		[ECR/293/Inst/HR/2013/RR-19]	
4	Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road Opp Civil Hospital Belagavi (Belgaum), Karnataka - 590002 India	Institutional Ethics Committee Dr. B.R. Ambedkar Road, Opp Civil Hospital Belagavi (Belgaum), Karnataka - 590002 India [ECR/142/Inst/KA/2019]	Dr. Abhishek T. Chavan
5	Prakhar Hospital Pvt., Ltd., 8/219 Arya nagar, Kanpur 208002 Uttar Pradesh, India	Institutional Ethics Committee Prakhar hospital Pvt. Ltd., 8/219 Arya nagar, Kanpur 208002 Uttar Pradesh, India [ECR/1017/Inst/UP/2017/RR-21]	Dr. V N Tripathi
6	Rana Hospital Pvt., Ltd., Rail Vihar Medical College Road Chargawa Gorakhpur- 273001, Uttar Pradesh, India	Institutional Ethics Committee Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road Chargawa Gorakhpur- 273001, Uttar Pradesh, India [EC/NEW/Inst/2019/7021]	Dr. Vishal Tripathi

In addition to point 3, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled "A Randomized, Double-Blind, Multi-Center, Phase III Study to assess and Compare the Immunogenicity and Safety of the 13-Valent Pneumococcal Polysaccharide Conjugate Vaccine (PCV13-TT) with Prevenar 13[®] of Pfizer Inc. in healthy infants in India" [Protocol no.: CRN_India/ 0106/2021, Version number: 2.0, Dated 01-03-2022]
- II. Firm shall submit complete safety and immunogenicity trial data from primary vaccination series of Pneumococcal Polysaccharide Conjugate Vaccine, I.P. (PCV13-TT) (Adsorbed) and obtain approval from this office before proceeding for booster dose administration as per SEC (vaccine) expert's recommendations dated 21.02.2022.
- III. Firm is required to submit the following documents/information:
 - a) Duly signed copy of 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.
 - b) copy of Insurance Certificate of subject trial.
- VIII. The firm is required to constitute a DSMB to review the safety data.
- IX. The formulation intended to be used in the clinical trial shall be manufactured using validated procedures under GMP conditions and shall have ongoing stability programme.
- X. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 01-JULY-2022

VENUGOPAL G SOMANI
Digital Controller, General (India)
Central Licensing Authority

Digitally signed by VENUGOPAL G SOMANI
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9113c, postalCode=110002, st=DELHI
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