

File No: BIO/CT/21/000044

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 G. C. Chemie Pharmie limited, 5/C, Shree Laxmi Indl. Estate, New Link Road, Andhderi (West), Mumbai – 400 053, E-Mail: regulatory@gccpl.com, to conduct clinical trial of the new drug or investigational new drug as per protocol number: CRN_India/ 2711/2020, version no. 1.0 dated 20-Oct-2020 in the below mentioned clinical trial sites.

CT No.: CT- 22/2021

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.

Place: New Delhi
Date: 16.07.2021

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

Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	23-valent Pneumococcal Polysaccharide Vaccine I.P.	
Therapeutic class:	Vaccine	
Dosage form:	Liquid injection for intramuscular route	
Composition:	Each 0.5 ml contains:	
	Active Ingredient	Quantity
	Serotypes of 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F & 33F	25 mcg
	Inactive ingredients	Quantity
	Sodium dihydrogen phosphate	30mcg
	Disodium hydrogen phosphate	35.5 mcg
	Sodium chloride	4.25 mg
	Water for injection	up to 0.5 ml
Indication:	For active immunization for prevention of Pneumococcal disease caused by the 23 serotype contained in the vaccine. The vaccine is for use in persons aged 18 years and above who are at increased risk for pneumococcal disease.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Prakhar Hospital Pvt. Ltd., 8/219 Arya Nagar, Kanpur, UP- 208 002	Ethics Committee Prakhar Hospital Pvt. Ltd., 8/219 Arya Nagar, Kanpur, UP- 208 002. ECR/1017/Inst/UP/2017	Dr. Jitendra Singh Kushwaha
2	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer – 305 001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer – 305 001, Rajasthan ECR/1156/Inst/RJ/2018	Dr. Veer bahadur Singh
3	Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargaawa Gorakhpur – 273 001	Institutional Ethics Committee, Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargaawa Gorakhpur – 273 001 ECR/1332/Inst/UP/2020	Dr. Ajeet Pratap Singh
4	All India Institute of Medical Science, Phulwari sarif, Patna, Bihar – 801 507	Institutional Ethics Committee, All India Institute of Medical Science, Phulwari sarif, Patna, Bihar – 801 507 ECR/1387/Inst/BR/2020	Dr. Chandramani Singh
5	Jeevan Rekha Hospital, Dr. BR Ambedkar Road,	Institutional Ethics Committee, jeevan Rekha Hospital, Dr. BR	Dr. Amit S. Bhate

	Belagavi – 590 002	Ambedkar Road, Belagavi – 590 002 ECR/1242/Inst/KA/2019	
6	Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Lakdikapool, Hyderabad – 500 004, Telangana.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad - 500 095, Telangana ECR/300/Inst/AP/2013/RR-19	Dr. N Ravi Kumar
7	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, jaipur, Rajasthan – 302 039	IEC Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, jaipur, Rajasthan – 302 039 ECR/1222/Inst/RJ/2019	Dr. Manish Kumar Jain

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

- I. The Phase III clinical trial should be conducted as per protocol titled “A Randomized, Double-blinded, Multicenter Phase III Clinical Trial to Evaluate the Immunogenicity and Safety of 23-Valent Pneumococcal Polysaccharide Vaccine in Healthy Adults” vide protocol number: CRN_India/ 2711/2020, version no. 1.0 dated 20-Oct-2020.
- II. The firm is required to constitute a DSMB to review the safety data.
- III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have ongoing stability programme.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 16.07.2021



(Dr. V. G. Somani)
Drugs Controller General (India)
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File No: BIO/CT/21/000044

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/21/000018

The Central Licencing Authority hereby grants licence to M/s G. C. Chemie Pharmie limited, 5/C, Shree Laxmi Indl. Estate, New Link Road, Andhderi (West), Mumbai – 400 053 to import new drug or investigational new drug for conduct of clinical trial as per protocol number: CRN_India/ 2711/2020, version no. 1.0 dated 20-Oct-2020 ~~or for examination, test and analysis in the below mentioned clinical trial sites or bioavailability or bioequivalence study centre.~~ [As per Annexure].

S. No	Name of the new drug to be imported	Therapeutic class of new drug	Quantity to be imported
1.	23-valent Pneumococcal Polysaccharide Vaccine IP	Vaccine	548 PFS

2. This license is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.
3. This license shall, unless previously suspended or revoked, be in force for a period of three years from the date of its issuance.
4. 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 – 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 – 653100 Telephone No.: 86-0877-2077789 FAX: 86-0877-2076918

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

Place: New Delhi
Date: 16.07.2021

(Dr. V. G. Somani)
Central Licencing Authority

Annexure:

Details of clinical trial sites:- Not applicable

Name of investigator	Address	Ethics committee details
Dr. Jitendra Singh Kushwaha	Prakhar Hospital Pvt. Ltd., 8/219 Arya Nagar, Kanpur, UP- 208 002	Ethics Committee Prakhar Hospital Pvt. Ltd., 8/219 Arya Nagar, Kanpur, UP- 208 002, ECR/1017/Inst/UP/2017
Dr. Veer bahadur Singh	Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer – 305 001, Rajasthan	Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer – 305 001, Rajasthan ECR/1156/Inst/RJ/2018
Dr. Ajeet Pratap Singh	Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargawa Gorakhpur – 273 001	Institutional Ethics Committee, Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargawa Gorakhpur – 273 001 ECR/1332/Inst/UP/2020
Dr. Chandramani Singh	All India Institute of Medical Science, Phulwari sarif, Patna, Bihar – 801 507	Institutional Ethics Committee, All India Institute of Medical Science, Phulwari sarif, Patna, Bihar – 801 507 ECR/1387/Inst/BR/2020
Dr. Amit S. Bhate	jeevan Rekha Hospital, Dr. BR Ambedkar Road, Belagavi – 590 002	Institutional Ethics Committee, jeevan Rekha Hospital, Dr. BR Ambedkar Road, Belagavi – 590 002 ECR/1242/Inst/KA/2019
Dr. N Ravi Kumar	Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Lakdikapool, Hyderabad – 500 004, Telangana.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad - 500 095, Telangana ECR/300/Inst/AP/2013/RR-19
Dr. Manish Kumar Jain	Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, jaipur, Rajasthan – 302 039	IEC Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyadhar Nagar, jaipur, Rajasthan – 302 039 ECR/1222/Inst/RJ/2019