

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 grant permission to M/s Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune, Off. Soli Poonawalla Road., Maharashtra (India) – 411028, Telephone No.: 020- 26993900, Fax No.: 020-26993921, E-Mail: regulatory@seruminstitute.com to conduct clinical trial of the new drug or investigational new drug “Trivalent Nanoparticle Influenza (tNIV) Vaccine” and “Covid Trivalent Influenza Combination (CIC) Vaccine” as per Protocol no. CIC-tNIV-01, Version: 4.0, Dated: 09-July-2025 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

**CT No.: CT-18/2025**

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 trials 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 with automatically be granted to you.

Date:  
Place: New Delhi

(Dr. Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licensing Authority

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

<b>Name of the new drug or investigational new drug:</b>	Trivalent Nanoparticle Influenza (tNIV) Vaccine & Covid Trivalent Influenza Combination (CIC) Vaccine.	
<b>Therapeutic class:</b>	Vaccine	
<b>Dosage form:</b>	Suspension for Intramuscular injection	
<b>Composition:</b>	<b>1. Trivalent Nanoparticle Influenza (tNIV) Vaccine</b>	
	<b>Each dose of 0.5 mL Vaccine contains:</b>	
	<b>Active Ingredients</b>	<b>Quantity</b>
	A/Wisconsin/67/2022 Influenza strain	30 mcg
	A/District of Columbia/27/2023 Influenza strain	30 mcg
	B/Austria/1359417/2021 Influenza strain	30 mcg
	<b>Inactive Ingredients</b>	<b>Quantity</b>
	Matrix-M	50 mcg
	Sodium Phosphate Dibasic Heptahydrate	10.5 mM
	Sodium Phosphate Monobasic Monohydrate	2 mM
	Sodium Chloride	127 mM
	L-Arginine Hydrochloride	15.5 mM
	α-Trehalose Dihydrate	0.75%
	Sodium Hydroxide and Hydrochloric Acid for pH adjustment	
	<b>2. Covid Trivalent Influenza Combination (CIC) Vaccine</b>	
	<b>Each dose of 0.5 mL Vaccine contains:</b>	
	<b>Active Ingredients</b>	<b>Quantity</b>
	SARS-CoV-2rS (JN.1 variant)	25 mcg
	A/Wisconsin/67/2022 Influenza strain	30 mcg
	A/District of Columbia/27/2023 Influenza strain	30 mcg
	B/Austria/1359417/2021 Influenza strain	30 mcg
	<b>Inactive Ingredients</b>	<b>Quantity</b>
	Matrix-M	50 mcg
Sodium Phosphate Dibasic Heptahydrate	10.5 mM	
Sodium Phosphate Monobasic Monohydrate	2 mM	
Sodium Chloride	127 mM	
L-Arginine Hydrochloride	15.5 mM	
α-Trehalose Dihydrate	0.75%	
Sodium Hydroxide and Hydrochloric Acid for pH adjustment		
<b>Indication:</b>	<p>tNIV: For active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B virus contained in the vaccine</p> <p>CIC vaccine: For active immunization for the prevention of flu and COVID-19 caused by influenza A subtype viruses and type B virus, and SARS-CoV-2 virus contained in the vaccine.</p>	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	KEM Hospital Research Centre Vadu Rural Health Program, Vadu Budruk, Taluka Shirur, Pune, Maharashtra- 412216, India.	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth, Pune-411011, Maharashtra. [ECR/272/Inst/MH/2013/RR-22]	Dr. Anand Kawade
2	School of Tropical Medicine, Department of Clinical and Experimental Pharmacology, Room no. 19 3rd floor, Administrative Building, Kolkata 700073, West Bengal, India.	Clinical Research Ethics Committee, School of Tropical Medicine, 108, CR Avenue, Kolkata 700073, West Bengal, India [ECR/194/Inst/WB/2013/RR-20]	Dr. Santanu Munshi
3	Hakeem Abdul Hameed centenary Hospital and Centre for Health Research and Development, Hamdard Institute of Medical Sciences and Research, Guru Ravidas Marg, Hamdard Nagar and Society for Applied Studies, 680, Gali No. 5, Nai Basti, Devli Gaon, New Delhi, Delhi- 110062.	Institutional Ethics Committee HIMSR and Associated HAH Centenary Hospital, Guru Ravidas Marg, Hamdard Nagar, South West Delhi, Delhi – 110062, India. [ECR/1597/Inst/DL/2021]	Dr. Vineet Jain
4	Bharati Vidyapeeth (Deemed to be University) Medical College Hospital & Research Centre, Clinical Research Unit, Pediatric OPD, Pune-Satara Road, Dhankawadi, Pune-411043, Maharashtra, India.	Institutional Ethics Committee Office, 4th floor, Bharati Hospital & Research Centre, Pune - Satara Road, Dhankawadi, Pune – 411043, Maharashtra, India. [ECR/313/Inst/MH/2013/RR-24]	Dr. Sonali Palkar
5	JSS Medical College, JSS Hospital, MG Road, Mysuru – 570004 Karnataka, India.	Institutional Ethics Committee JSS Medical College, JSS Hospital Sri Shivarathreeshwara Nagara, Mysuru Karnataka-570015. [ECR/387/Inst/KA/2013/RR-22]	Dr. Praveen Kulkarni
6	Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Rajiv Gandhi Salai. Kelambakkam, Chengalpattu dt, Tamil Nadu 603103, India.	CARE -IHEC for Faculty research Chettinad academy of research and education, Chettinad health City, Rajiv Gandhi Salai, Kelambakkam, Chengalpattu dt, Tamil Nadu -603103 [ECR/1589/Inst/TN/2021]	Dr. Arun Kumar R
7	Department of Community Medicine, School of Public Health, PGIMER, Chandigarh-160012, India.	Institutional Ethics Committee Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th	Dr. Madhu Gupta

		Floor, P N Chuttani Block, Chandigarh – 160012 India. [ECR/25/Inst/CH/2013/RR-20]	
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In addition to point 4, the permission is subject to following condition(s):

- I. The clinical trial should be conducted as per approved protocol titled “A Phase II/III, multicentre, observer-blind, randomized, active controlled study to evaluate immunogenicity and safety of a trivalent nanoparticle influenza vaccine and Covid-Influenza Combination Vaccine compared with licensed influenza and Covid -19 vaccines in adults. (Protocol no: CIC-tNIV-01, Version no. 4.0 dated 09 July 2025).
- II. The formulation intended to be used in clinical trial shall be manufactured under GMP conditions and shall be tested by CDL, Kasauli.
- III. To submit Ethics Committee approval for proposed Phase II/III Clinical trial.
- IV. To submit report of Phase II part of clinical study along with DSMB recommendation to CDSCO for review before proceeding to Phase III part of study.
- V. To submit updated stability data of three consistency batches before initiation of phase-III part of study.
- VI. To submit process validation data before initiation of phase-III part of study
- VII. To submit technology transfer report incorporating PPQ results of CIC and tNIV.
- VIII. To submit detailed characterization report for Phase III batches including Western Blot, SRID, Peptide Mass fingerprinting, MALDI-TOF, SDS Page data with detailed conclusion.
- IX. To submit valid Ethics committee registration certificate for School of Tropical Medicine, 108, CR Avenue, Kolkata700073, West Bengal, India and Post Graduate Institute of Medical Education and Research Room No. 6006, IEC Office, 6th Floor, P N Chuttani Block, Chandigarh –160012,India.

Date:  
Place: New Delhi

(Dr.Rajeev Singh Raghuvanshi)  
Drugs Controller General (India)  
Central Licensing Authority

