

File No: BIO/CT/21/000065

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 Dr. Rahul Shashidhar Kulkarni of M/s Sanofi Healthcare India Private Limited Sanofi House, C.T.S-117B, L & T Business Park, Saki Vihar Road, Powai Mumbai – 400072, Maharashtra.:4066301200, FAX:4066301200 E-mail: shantha.ra@sanofi.com to conduct clinical trial of the new drug or investigational new drug as per Study Code: GQM00023, Protocol Version Number: 2.0, Dated 22-February-2021 in the below mentioned clinical trial sites.

**CT No.: CT- 35/2021**

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.
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.

Place: New Delhi  
Date: 12-Oct-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	Quadrivalent Influenza vaccine (Split Virion, Inactivated)	
Therapeutic class	Vaccine	
Dosage form	Suspension for injection in a pre-filled syringe	
Composition	Each single dose of 0.5 ml contains:	
	<b>Active ingredient</b>	<b>Quantity</b>
	Hemagglutinin A (H1N1)	15 µg
	Hemagglutinin A (H3N2)	15 µg
	Hemagglutinin B /(Victoria Lineage)	15 µg
	Hemagglutinin B /( Yamagata Lineage)	15 µg
	<b>Inactive Ingredients</b>	
	PBS	q.s.
Indication	For active immunization against Influenza Disease.	

**Details of clinical trial sites:**

Sl. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Prakhar Hospital Pvt. Ltd8/219 Arya Nagar Kanpur- 208002,U.P. India	IEC Prakhar Hospital Pvt Ltd., Prakhar Hospital Pvt. Ltd8/219 Arya Nagar Kanpur KanpurKanpur Nagar UttarPradesh -208002 India [ECR/1017/Inst/UP/2017/RR-21]	Dr. Virendra Nath Tripathi
2	Department of Community Medicine Kalinga Institute of Medical Sciences Kushabhadra campus(Campus 5) KIIT University, Patia Bhubaneswar Khordha Odisha - 751024 India	Institutional Ethics Committee-KIMS Kalinga Institute of Medical SciencesKushabhadra campus(Campus 5) KIIT University, Patia Bhubaneswar Khordha Orissa - 751024 India [ECR/321/Inst/OR/2013/RR-20]	Dr. Sonali Kar
3	Dept. of Community &Family Medicine,All India Institute of Medical Science(AIIMS),Phulwaris harif,Patna, Bihar- 801507, India.	IEC Aiims-Pall India Institute of Medical Sciences, Patna Phulwarisha Rif Patna Bihar - 801507 India [ECR/1387/Inst/BR/2020]	Dr. Chandramani Singh
4	KEM Hospital Research Centre, Vadu Rural Health Program At Post  Vadu Budruk, Taluka Shirur, District Pune 412216, India	KEM Hospital Research Centre Ethics Committee KEM Hospital Ressearch centreTDH BUILDING Ras1a peth IIIRD FILOOR. 303 PunePune Maharashtra - 411011 India [ECRJ27211nstIMHJ20131RR-19]	Dr. Anand Shantaram Kawade
5	Cheluvamba Hospital, Mysore Medical College and Research Institute,	Institutional Ethics Committee, Cheluvamba Hospital, Mysore Medical College and Research	Dr. Prashanth S

Irwin Road, Mysore-570001, Karnataka, India.	Institute, Irwin Road, Mysore-570001, Karnataka, India. ECR/134/Inst/KA/2013/RR-19]	
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In addition to point 4, the permission is subject to following conditions:

- I. The Phase III clinical trial shall be conducted as per approved protocol titled " Immunogenicity and Safety of the Quadrivalent Inactivated Split-Virion Influenza Vaccine in Participants 6 Months of Age and Older in India." [Study Code: GQM00023, Protocol Version Number: 2.0, Dated 22-February-2021]
- II. DSMB shall be constituted for the evaluation of safety data of the clinical trial.
- III. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures.

Place: New Delhi  
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(Dr. V. G. Somani)  
Drugs Controller General (India)  
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