File No: BIO/CT/20/000065
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 Ms. Mona Gogia of M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road Dholka Dholka (India) - 387810 Telephone No.: 2714-221481 FAX: 2714- 220315 E-Mail: mona.gogia@cadilapharma.co.in, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: CRSC20002, version no.: 2.0, dated 20th April, 2021** in the below mentioned clinical trial sites.

CT No.: CT- 15/2021

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.

VENUGOPAL GIRDHARILAL SOMANI

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

Place: New Delhi
Date: 03-June-2021

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CDSCO CDSCO CENTRAL DRUGS STANDARD CONTROL ORGANIZATION सत्यमेव जयते MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for intramuscular injection	
Composition:	Each dose 0.5 mL of Vaccine contains:	
	Active ingredient	**Quantity**
	A/Brisbane/02/2018 (H1N1) pdm 09-like virus	15 µg
	A/Kansas/14/2017 (H3N2)-like virus	15 µg
	B/Colorado/06/2017-like virus (B/Victoria/2/87lineage)	15 µg
	B/Phuket B/Phuket/3073/2013 (B/Yamagata lineage)-like virus	15 µg
	Calcium chloride dehydrate	22.05 µg
	Polysorbate 80	0.05mg
	Disodium Hydrogen phosphate anhydrous	1.50mg
	Sodium dihydrogen phosphate monohydrate	0.257 mg
	Sodium Chloride	14.61mg
	Water for injection	q.s. 0.5mL
Indications:	For active immunization of children from 6 months and adults upto 65 years of age against disease caused by influenza virus that pose a pandemic threat to humans.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	AIIMS Raipur, Great Eastern Rd, AIIMS Campus, Tatibandh, Raipur, Chhattisgarh- 492099, India.	Institute of Ethics Committee, AIIMS Raipur, Great Eastern Rd, AIIMS Campus, Gate no-05,Tatibandh, Raipur, Chhattisgarh-India.492099 [EC Registration no.: ECR/714/Inst/CT/2015/RR-18]	Dr. Atul Jindal
2.	SSG Hospital, Jail Rd, Indira Avenue, Vadodara, Gujarat-390001, India.	Institute of Ethics Committee for Human Research, 1st Floor New Library Building,Medical College & SSG Hospital Baroda-390001 [EC Registration no.: ECR/85/Inst/GJ/2013/RR-18]	Dr. Paresh Kumar Thakkar
3.	Panimalar Medical College Hospital & Research Institute	Institute of Ethics Committee, Panimalar Medical College	Dr. A Ramanath

	Varadharajapuram, Poonamallee, Chennai - 600 123 India.	Hospital & Research Institute Varadharajapuram, Poonamallee, Chennai - 600 123 India.	
4.	Grant Govt. Medical College & Sir JJ Group of Hospitals, Mumbai, Maharashtra-400008, India	Institute of Ethics Committee, GGMC, Grant Govt. Medical College & Sir JJ Group of Hospitals, Mumbai, Maharashtra-400008, India. [EC Registration no.: ECR/382/Inst/MH/2013/RR-19]	Dr. Mane Sushant Satish
5	Downtown Hospital, GS Rd, Bormotoria, Guwahati, Assam 781006, India.	Institute of Ethics Committee, Downtown Hospital, GS Rd, Bormotoria, Guwahati, Assam 781006, India. [EC Registration no.: ECR/549/Inst/AS/2014/RR-17]	Dr. Nitin Agarwal
6	D Y Patil Medical College and Research Center 11, Ayyappa Rd, Dr. D Y Patil Vidyanagar, Sector 5, Nerul, Navi Mumbai, Maharashtra-400706.	Institute of Ethics Committee, D Y Patil Medical College and Research Center 11, Ayyappa Rd, Dr. D Y Patil Vidyanagar, Sector 5, Nerul, Navi Mumbai, Maharashtra-400706. [EC Registration no.: ECR/195/Inst/MH/2013/RR-19]	Dr. Amit Saxena

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

I. The proposed Phase III clinical trial should be carried out as “Double Blind” as per SEC (Vaccine) recommendations dated 04-Feb-2021 and the remaining protocol should be as per the protocol no. CRSC20002, version no.: 2.0, dated 20th April, 2021.
II. Firm is required to submit Form CT-11 for clinical trial purpose as per the provisions of ND & CTs Rules, 2019 before initiating the clinical trial.
III. Firm is required to submit Form-29 for clinical trial purpose as per the provisions of ND & CTs Rules, 2019 before initiating the clinical trial.
IV. DSMB to be constituted for review of safety data of proposed Phase III Clinical Trial.
V. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions
VI. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 03-June-2021

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