

File No: BIO/CT/21/000169
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 Mr. Sanjay Maheshwari of M/s Cadila Healthcare Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad (India) - 382213 Telephone No.: null Fax: null e-mail: sanjaymaheshwari@zyduscadila.com, to conduct clinical trial of the new drug or investigational new drug as per Protocol No. 21-13, Version no. 00, Dated 07-DEC-2021 in the below mentioned clinical trial sites.

CT No.: CT-11 /2022

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: 21-April-2022

**VENUGOPAL
G SOMANI**

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(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
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Annexure:**Details of New Drug or Investigational New Drug:**

Name of the new drug or investigational new drug:	Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent)	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for Intramuscular injection	
Composition:	Each dose of 0.5 ml vaccine contains:	
	Ingredients	Quantity
	A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus	≥ 15µg HA
	A/Hong Kong/2671/2019 (H3N2)-like virus	≥ 15µg HA
	B/Washington/02/2019-like virus	≥ 15µg HA
	B/Phuket/3073/2013 like Virus	≥ 15µg HA
	Propagated in fertilized hen's eggs from healthy chicken flocks Inactivated by Betapropiolactone.	
Indications:	The vaccine indicated in 6 months to 35 months for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Department of Paediatrics, Post-graduate Institute, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pimpri-Chinchwad, Pune, Maharashtra-411018, India.	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune - 411018, Maharashtra. (ECR/1236/Inst/MH/2019)	Dr. Deepali Abhijit Ambike
2	Department of Pediatrics Niloufer Hospital (Affiliated to Osmania Medical College), Red Hills, Lakdikapool, Hyderabad-500004, Telangana.	Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad – 500095, Telangana (ECR/300/Inst/AP/2013/RR-19)	Dr. N. Ravi Kumar
3	Institute of child health, 11, Dr Biresh Guha Street, Kolkata-700017, West Bengal, India	Ethics Committee, Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata – 700017, West Bengal (ECR/359/Inst/WB/2013/RR-19)	Dr. Monjori Mitra
4	Department of Pediatrics King George	Institutional Ethics Committee, Office of Research Cell,	Dr. Nishant Verma

	Medical Chowk, 226003	University Lucknow-	Administrative Block, King George's Medical University, Lucknow-226003, Uttar Pradesh. (ECR/262/Inst/UP/2013/RR-19)	
5	Institute of Medical sciences & SUM Hospital, K8, Kalinga Nagar, Ghatikia, Bhubaneswar - 751003, Odisha		Institutional Ethics Committee, IMS & SUM Hospital, K8, Kalinga Nagar, Ghatikia, Bhubaneswar 751003, Odisha ECR/627/Inst/OR/2014/RR-20]	Dr. Dilip Kumar Dash

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

1. The Phase III clinical trial should be conducted as per title "A prospective, randomized, two arm, parallel, active controlled, multicentre, phase III clinical study to compare the immunogenicity and safety of Inactivated Influenza vaccine (split virion) I.P. (Tetravalent) 0.5 ml of M/s Cadila Healthcare Limited with Fluarix -Tetra of M/s GlaxoSmithKline Pharmaceuticals Limited in healthy children aged 6 to 35 months" [Protocol No. 21-13, Version no. 00, Dated 07-DEC-2021].
2. DSMB is required to be constituted to review the safety data of phase III clinical trial.
3. The firm is required to submit the following information/documents:
 - a) 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 the Insurance Certificate.
4. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and using validated procedures and shall have ongoing stability program.
5. Only CDL, Kasauli certified batches shall be used in the clinical trial.

Place: New Delhi
Date: 21-April-2022

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