

File No: BIO/CT/25/000113  
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 Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47, 49 & 50, Opp. Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Village - Changodar, Taluka - Sanand, Dist. - Ahmedabad, Gujarat (India) – 382213 Telephone No.: 91-2717-664600 FAX: 91-2717-664600 to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: VFLU.25.001 Version No. 02 Protocol Date 22.12.2025 in the below mentioned clinical trial sites.

**CT No.: CT- 03/2026**

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:

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

**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. (Trivalent) in Single dose (0.5 ml)						
Therapeutic class:	Vaccines						
Dosage form:	Liquid (Single dose) vaccine for intramuscular route of administration.						
Composition:	<p>Composition:  <b>Each dose of 0.5 ml contains:</b></p> <table border="1"> <tr> <td>A/Victoria/4897/2022 (H1N1) pdm09 – like virus</td> <td>≥ 15 µg HA*</td> </tr> <tr> <td>A/Croatia/10136RV/2023 (H3N2) – like virus</td> <td>≥ 15 µg HA*</td> </tr> <tr> <td>B/Austria/1359417/2021 (B/Victoria lineage) – like virus</td> <td>≥ 15 µg HA*</td> </tr> </table> <p>Propagated in fertilized hen's eggs from healthy chicken flocks  Inactivated by β-propiolactone.  *Haemagglutinin</p>	A/Victoria/4897/2022 (H1N1) pdm09 – like virus	≥ 15 µg HA*	A/Croatia/10136RV/2023 (H3N2) – like virus	≥ 15 µg HA*	B/Austria/1359417/2021 (B/Victoria lineage) – like virus	≥ 15 µg HA*
A/Victoria/4897/2022 (H1N1) pdm09 – like virus	≥ 15 µg HA*						
A/Croatia/10136RV/2023 (H3N2) – like virus	≥ 15 µg HA*						
B/Austria/1359417/2021 (B/Victoria lineage) – like virus	≥ 15 µg HA*						
Presentation:	0.5 ml (Single Dose)						
Indication(s):	In Children from 6 months to 17 years 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.	Pulse Multispeciality Hospital, Survey No. 51/7/B/1 Vishwa Arcade, Bombay Bangalore Highway, At Post Narhe, Pune - 411041, Maharashtra	<p>Ethics Committee of Pulse Multispecialty Hospital, Survey No. 51/7/B/1 Vishwa Arcade, Bombay Bangalore Highway, At Post Narhe, Pune - 411041, Maharashtra</p> <p>Registration No:  ECR/1339/Inst/MH/2020/RR-25</p>	Dr. Prashant Khandgave
2.	Aatman Hospital, 5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal - Ghuma Main Road, Bopal, Ahmedabad - 380058, Gujarat.	<p>Institutional Ethics Committee, Aatman hospital, 5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal – Ghuma Main Road, Bopal, Ahmedabad - 380058, Gujarat.</p> <p>Registration No:  ECR/1565/Inst/GJ/2021</p>	Dr. Shreyans Shah

3.	KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru nagar Belagavi – 590010 Karnataka India	Institutional Ethics Committee, KLE University's KLE Dr PK Hospital & MRC, Nehrunagar Belagavi - 590010 Karnataka. Registration No: ECR/211/Inst/KA/2013/RR-24	Dr. Mahantesh Patil
4.	Baramati Hospital Pvt Ltd., Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati, Pune - 413102, Maharashtra	Baramati Hospital Pvt Ltd., Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati, Pune – 413102, Maharashtra.  Registration No: ECR/1449/Inst/MH/2020	Dr. Bhaskar Vilasrao Jedhe - Deshmukh
5.	MAM,S SSAM'S Sane Guruji Arogya Kendra, Malwadi Hadapsar, Pune – 411028, Maharashtra.	Supreme Independent Ethics Committee, Opposite to SP Info city, Pune Saswad Highway, Behind Reddy Hotel, Hadapsar, Pune – 412308, Maharashtra  Registration No: ECR/378/Indt/MH/2023	Dr. Badge Ganesh Shivmurti
6.	Hi-Tech Medical College & Hospital, Pandra, Rasulgarh, Bhubaneswar - 751025, Khordha, Orissa.	Institutional Ethics Committee, Hi-Tech Medical College and Hospital Health Park, Pandara, Rasulgarh, Bhubaneswar - 751025, Khordha, Orissa.  Registration No: ECR/273/Inst/OR/2013/RR-20	Dr. Lisa Sarangi
7.	King George's Medical University, Shahmeena Road, Chowk, Lucknow - 226003, Uttar Pradesh	Institutional Ethics Committee, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow - 226003, Uttar Pradesh.  Registration No: ECR/262/Inst/UP/2013/RR-24	Dr. D. Himanshu
8.	Department of Pediatrics, GMERS Medical College and Civil Hospital, Near Gujarat High Court, S.G. Highway, Sola, Ahmedabad – 380060, Gujarat	Institutional Ethics Committee, GMERS MC Sola, Department of pharmacology, 4th floor, college building, Sola, Ahmedabad – 380061, Gujarat  Registration No: ECR/404/Inst/GJ/2013/RR-20	Dr. Nehal Patel

9.	Belagavi Institute of Medical Sciences, Dr B.R. Ambedkar Road, Sadashiv Nagar, Belagavi – 590001, Karnataka	Institutional Ethics Committee, Belagavi Institute of Medical Sciences, Dr B.R. Ambedkar Road, Sadashiv Nagar, Belagavi – 590001, Karnataka  Registration No: ECR/801/Inst/KA/2016/RR-20	Dr. R.G. Viveki
10.	Department of Community Medicine and Family Medicine, All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar - 751019, Orissa.	Institutional Ethics Committee, All India Institute of Medical Sciences, Sijua, Patrapada, Bhubaneswar - 751019, Orissa.  Registration No: ECR/534/Inst/OD/2014/RR-25	Dr. Swayam Pragyna Parida
11.	North Bengal Medical College and Hospital, Sushrutanagar, Siliguri, Darjeeling- 734012	Institutional Ethics Committee, North Bengal Medical College and Hospital, Sushrutanagar, Darjeeling- 734012  Registration No: ECR/1701/Inst/WB/2022	Dr. Madhumita Nandi
12.	Marwari Hospitals, S.J Road, Athgaon, Guwahati, Assam -781008	ECRC-HEC, Marwari Hospitals, S.J Road, Athgaon, Guwahati, Assam -781008  Registration No: ECR/487/Inst/AS/2013/RR-24	Dr. Suresh Kumar Jain

In addition to point 3, the permission is subject to following conditions:

1. The clinical trial should be conducted as per approved protocol titled “A prospective, single-arm, multicentre, phase IV clinical trial to evaluate the immunogenicity and safety of Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) of M/s. Zydus Lifesciences Ltd. in healthy pediatric participants aged 6 months to 17 years”. Protocol No.: VFLU.25.001 Version No. 02 Protocol Date 22.12.2025.
2. The firm is required to constitute a DSMB to review the safety data.
3. Firm shall submit Ethics Committee approval for proposed Phase-IV Clinical trial.

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

Place: New Delhi  
Date: