

File No: BIO/CT/24/000048

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 Zydus Lifesciences Limited, Plot Survey No. 23, 25/P, 37, 40/P, 42 to 47,49 & 50, Sarkhej-Bavla N.H.No. 8A, Opp. Ramdev Masala, Village – Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) - 382213, Telephone No.: 02717664600, Fax: 02717664600 E-mail: sanjaymaheshwari@zyduslife.com conduct clinical trial of the new drug or investigational new drug as per Protocol No.: 24-02, Version no. 00 dated 09/03/2024 to conduct clinical trial of the new drug or investigational new drug as per below mentioned clinical trial sites.

CT No.: CT-10/2024

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.

Date:
Place: New Delhi

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

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Measles and Rubella Vaccine (Live) LP. (Freeze Dried) in Multidose vial (2.5 ml — 5 dose)	
Therapeutic class:	Vaccine	
Dosage form:	Freeze dried vaccine for Subcutaneous Injection upon reconstitution.	
Composition:	Each dose of 0.5 mL after reconstitution contains:	
	Active ingredient	Quantity
	Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells)	NLT 1000 CCID ₅₀
	Live Attenuated Rubella Virus (RA 27/3 strain) (Propagated on Human Diploid Cells)	NLT 1000 CCID ₅₀
	Inactive ingredient	
	Gelatin	3.92 mg
	D-Sorbitol	7.84 mg
	D-Lactose monohydrate	4.70 mg
	Lactalbumin Hydrolysate	0.54 mg
	Calcium gluconate	2.24 mg
	L-Alanine	0.14 mg
	L-Histidine	0.32 mg
	Tricine	0.46 mg
Sterile Water for injections I.P (Diluent)	2.5 ml	
Indication:	For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously.	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Yashwantrao Chavan Memorial (YCM) Hospital, Sant Tukaram Nagar, Pimpri, Pimpri-Chinchwad, Pune - 411018, Maharashtra.	Institutional Ethics Committee, Yashwantrao Chavan Memorial Hospital, Sant Tukaram Nagar, Pimpri, Pune - 411018, Maharashtra. [ECR/1236/Inst/ MH/2019]	Dr. Deepali Ambike.
2	GMERS Medical College, Sola, S.G. Highway, Near New Gujarat High Court, Ahmedabad Gujarat- 380061	Institutional Ethics Committee ,GMERS Medical College, and Civil Hospital Sola, Ahmedabad Gujarat - 380061 [ECR/404 /Inst/GJ /2013/RR-20]	Dr. Nehal Patel
3	King George's Medical University, Shahmeena Road, Chowk, Lucknow- 226003	Institutional Ethics Committee, Office of Research Cell, Administrative Block, King George's Medical University, Lucknow-226003, Uttar Pradesh	Dr. Shakal Narayan Singh

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	Uttar Pradesh	[ECR/262/Inst/UP/2013/RR-19]	
4	Medical College & Hospital, Kolkata, 88, College Street, Kolkata - 700073, West Bengal	Institutional Ethics Committee for Human Research, Medical College, Kolkata, 88, College Street, Kolkata - 700073, West Bengal [ECR/287/Inst/WB/2013/RR- 19]	Dr. Kalpana Datta
5	Hi-Tech Medical College & Hospital, Health Park, Pandra, Rasulgarh, Bhubaneswar – 751025, Odisha	Institutional Ethics Committee, Hi-Tech Medical College & Hospital, Health Park, Pandara, Rasulgarh, Bhubaneswar –751025, Odisha [ECR/273/Inst/OR/2013/RR-20]	Dr. Lisa Sarangi
6	Institute of Child Health, 11, Dr. Biresh Guha Street, Kolkata -700017, West Bengal	Institutional 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
7	Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow - 226010, Uttar Pradesh	Institutional Ethics Committee, Dr. Ram Manohar Lohia Institute of Medical Sciences, Vibhuti Khand, Gomti Nagar, Lucknow - 226010, Uttar Pradesh [ECR/913/Inst/UP/2017/RR-20]	Dr. Neha Thakur Rai
8	Medical College Baroda and S.S.G. Hospital, Indira Avenue, Jail Road, Vadodara – 390001, Gujarat	Institutional Ethics Committee for Human Research, Medical College Baroda and S.S.G. Hospital, Indira Avenue, Jail Road, Vadodara – 390001, Gujarat [ECR/85/Inst/GJ/2013/RR-24]	Dr. Paresh Thakkar
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 [ECR/801/Inst/K A/2016/RR-20]	Dr. Jyothi S. Doshetty
10	Indira Gandhi Government Medical College and Mayo Hospital, Central Avenue Road Road, Nagpur -440018, Maharashtra	Institutional Ethics Committee, Department of Pharmacology, Indira Gandhi Government Medical College, Central Avenue Road, Nagpur - 440018, Maharashtra [ECR/485/Inst/ MH/2013/RR-20]	Dr. Milind Suryawanshi
11	Health 1 Super Speciality Hospital, Near Venitian Villa, Shilaj Circle, S.P. ring road, Thaltej, Ahmedabad, Gujarat-380059	Ethics Committee, Health 1 Super Speciality Hospital, S.P. Ring road, Near Shilaj Circle, Shilaj, Ahmedabad - 380059, Gujarat [ECR/1666/Inst/ GJ/2022]	Dr. Purva Jitendrakumar Shah
12	Baramati Hospital Private Ltd., Behind Kavivarya, Moropant Natyamandir, Ring Road,	Ethics Committee, Baramati Hospital Private Ltd., Behind Kavivarya, Moropant Natyamandir, Ring Road, Baramati – 413102, Dist.	Dr. Bhaskar V Jedhe Deshmukh

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	Baramati – 413102, Dist. Pune, Maharashtra	Pune, Maharashtra [ECR/1449/Inst/ MH/2020]	
13	Pulse Multispeciality Hospital, Vishwa Arcade, Mumbai Bangalore Highway, Narhe, Ambegaon, Pune - 411041, Maharashtra	Institutional Ethics Committee, Pulse Multispeciality Hospital, Vishwa Arcade Mumbai Bangalore Highway, Narhe, Pune - 411041, Maharashtra [ECR/1339/Inst/ MH/2020]	Dr. Prashant Khandgave
14	Mogre Children Hospital, Tajshree Govind Complex, Sakkardara Square, Nagpur - 440024, Maharashtra	Swasthyam Ethics Committee, Swasthyam Superspeciality Hospital, Plot No. 97,98, CTO Staff Coop Housing Society, Vivekanand Nagar, Near Sai Mandir, Wardha Road, Nagpur- 440015, Maharashtra. [ECR/1558/Inst/MH/2021]	Dr. Sandeep Mogre
15	Aatman Hospital,5, Anveshan Row House, Opp. Umiya Mata Mandir, Bopal-Ghuma Main Road, Bopal, Ahmedabad-380058, Gujarat	Institutional Ethics Committee, Aatman Hospital, 5, Anveshan Row house, opp. Umiya mata mandir, Bopal-Ghuma Main Road, Bopal, Ahmedabad-380058, Gujarat [ECR/1565/Inst/ GJ/2021]	Dr. Shreyans Shah
16	KLES Dr Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi - 590010, Karnataka	Institutional Ethics Committee, KLE University, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belagavi – 590010, Karnataka [ECR/211/Inst/KA/2013/RR-19]	Dr. Mahantesh Patil

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

- I. The Phase IV clinical trial should be conducted as per title “A prospective, randomized, parallel, single-blind, four-arm, active-controlled, multicentre, phase IV clinical trial to evaluate the immunogenicity and safety of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. and to evaluate lot-to-lot consistency of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. in healthy infants aged 9-12 months [Protocol No.: 24-02, Version no.00 dated 09/03/2024]
- II. DSMB is required to be constituted to review the safety data of phase IV clinical trial.
- III. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
- IV. Only CDL, Kasauli certified batches shall be used in the clinical trial.
- V. Ethics Committee approval of said clinical trial is required to be submitted.

Date:
Place: New Delhi

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