

File No: BIO/CT/25/000048
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Vaccine division)

FDA Bhawan Kotla Road,
New Delhi-110002

From:

The Drugs Controller General, India,
Central Drugs Standard Control Organization,
Directorate General of Health Services,
Government of India

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.

Subject: Permission for conducting a Phase I clinical trial titled "An open-label, single-treatment, single-period, single dose, clinical phase I study to assess the safety and tolerability of measles, mumps, rubella & varicella vaccine (live attenuated, freeze dried) of M/s. Zydus life sciences Ltd. in healthy, adult, human participants" (Protocol No. ZYMMRV 1002, Version No. 03, dated 14/02/2026) - reg.

Reference: Your Application No. BIO/CT04/FF/2025/48777 dated 07.04.2025 on the subject mentioned above.

Sir,

Please refer to your application no. BIO/CT04/FF/2025/48777 dated 07.04.2025, received by this office on the above subject. Please find enclosed herewith permission to conduct a Phase I Clinical Trial of Measles, Mumps, Rubella and Varicella vaccine (Live attenuated, Freeze dried)" in Form CT-06 under the New Drugs and Clinical Trials Rules, 2019 along with the details of new drug and clinical trial sites.

Please acknowledge receipt of the same.

Yours faithfully,

RAJEEV SINGH
RAGHUVANSHI

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**(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)**

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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. 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, Tal.: Sanand, Dist.: Ahmedabad – 382213, State: Gujarat, (India), Tel.No.:02717664605, Fax: 02717664600, E-Mail: sanjaymaheshwari@zyduslife.com to conduct clinical trial of the new drug or investigational new drug as per protocol number: ZYMMRV 1002, Ver. 03 dated 14.02.2026 in the below mentioned clinical trial sites.

CT No.: CT- 10/2026

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:

RAJEEV SINGH
RAGHUVANSHI
(Dr. Rajeev Singh Raghuvanshi)
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:	Measles, Mumps, Rubella and Varicella vaccine (Live attenuated, Freeze dried)																																				
Therapeutic class:	Vaccine																																				
Dosage form:	Freeze dried vaccine (injection)																																				
Composition:	<p>Each dose of 0.5 ml after reconstitution contains:</p> <table border="1"> <thead> <tr> <th>Ingredients</th><th>Quantity</th></tr> </thead> <tbody> <tr> <td colspan="2">Active ingredients</td></tr> <tr> <td>Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells)</td><td>NLT $10^{3.0}$ CCID₅₀</td></tr> <tr> <td>Live Attenuated Mumps Virus (Hoshino Strain) (Propagated on Chick Fibroblast Cells)</td><td>NLT $10^{4.01}$ CCID₅₀</td></tr> <tr> <td>Live Attenuated Rubella Virus (RA 27/3 strain) (Propagated on Human Diploid Cells)</td><td>NLT $10^{3.0}$ CCID₅₀</td></tr> <tr> <td>Live attenuated Varicella Zoster virus (OKA Strain) (Propagated on Human Diploid Cells)</td><td>NLT $10^{3.3}$ PFU</td></tr> <tr> <td colspan="2">Inactive ingredients</td></tr> <tr> <td>D-Lactose monohydrate</td><td>44.00 mg</td></tr> <tr> <td>D-Mannitol</td><td>27.50 mg</td></tr> <tr> <td>Dextran 40</td><td>27.50 mg</td></tr> <tr> <td>Trehalose dihydrate</td><td>22.00 mg</td></tr> <tr> <td>Human Albumin solution</td><td>5.50 mg</td></tr> <tr> <td>Sodium glutamate monohydrate</td><td>2.20 mg</td></tr> <tr> <td>Disodium Edetate</td><td>0.55 mg</td></tr> <tr> <td>Disodium hydrogen phosphate dihydrate</td><td>1.10 mg</td></tr> <tr> <td>Potassium dihydrogen phosphate</td><td>0.55 mg</td></tr> <tr> <td colspan="2">Diluent for reconstitution</td></tr> <tr> <td>Sterile Water for injection I.P.</td><td>0.50 ml</td></tr> </tbody> </table>	Ingredients	Quantity	Active ingredients		Live Attenuated Measles Virus (Edmonston Zagreb Strain) (Propagated on Human Diploid Cells)	NLT $10^{3.0}$ CCID ₅₀	Live Attenuated Mumps Virus (Hoshino Strain) (Propagated on Chick Fibroblast Cells)	NLT $10^{4.01}$ CCID ₅₀	Live Attenuated Rubella Virus (RA 27/3 strain) (Propagated on Human Diploid Cells)	NLT $10^{3.0}$ CCID ₅₀	Live attenuated Varicella Zoster virus (OKA Strain) (Propagated on Human Diploid Cells)	NLT $10^{3.3}$ PFU	Inactive ingredients		D-Lactose monohydrate	44.00 mg	D-Mannitol	27.50 mg	Dextran 40	27.50 mg	Trehalose dihydrate	22.00 mg	Human Albumin solution	5.50 mg	Sodium glutamate monohydrate	2.20 mg	Disodium Edetate	0.55 mg	Disodium hydrogen phosphate dihydrate	1.10 mg	Potassium dihydrogen phosphate	0.55 mg	Diluent for reconstitution		Sterile Water for injection I.P.	0.50 ml
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Indication(s):	For active immunization for prevention of Measles, Mumps, Rubella and Varicella Virus Infection.																																				

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Zydus Research Centre, Clinical Research Department, Survey No. 396/403, Sarkhej-Bavla N.H. No. 8A, Moraiya, Ahmedabad-382213, Gujarat, India.	<p>Riddhi Medical Nursing Home Institutional Ethics Committee, Riddhi Medical Nursing Home, A/101 Jalaram Plaza Jawahar Chowk, Maninagar, Ahmedabad Gujarat - 380008 India</p> <p>ECR/886/Inst/GJ/2016/RR-24</p>	Dr. Krunal Prajapati

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

- I. The Phase-I clinical trial should be conducted as per approved protocol titled, "An open-label, single-treatment, single-period, single dose, clinical phase I study to assess the safety and tolerability of measles, mumps, rubella & varicella vaccine (live attenuated, freeze dried) of M/s. Zydus life sciences Ltd. in healthy, adult, human participants (Protocol No. ZYMMRV 1002, Version No. 03, dated 14/02/2026)".
- II. The formulation intended to be used in the Phase-I clinical trial shall be manufactured under GMP Conditions.
- III. Only CDL, Kasauli certified batches shall be used in the Phase-I clinical trial.
- IV. To submit Ethics Committee approval for the clinical trial.
- V. To submit test report from CDL, Kasauli.

RAJEEV SINGH
RAGHUVANSHI

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

Place: New Delhi
Date:

