File No: BIO/CT/25/000115
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, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Taluka - Sanand, Dist. – Ahmedabad – 382213, State: Gujarat, India, Telephone No.: 02717664605, FAX: 02717664600 E-Mail: sanjaymaheshwari@zyduslife.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: ZYCHIK 1001, Version 03 dated 30.01.2026.

CT No.: CT- 06/2026

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.

RAJEEV SINGH RAGHUVANSHI
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Date: 2026.04.20 15:26:48 +05'30'

Place: New Delhi
Date:

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

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Inactivated Chikungunya Vaccine in Single dose vial (0.5 ml).</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Vaccine (Liquid), Intramuscular route of administration.</td></tr>
<tr><td>Composition:</td><td>Each dose of 0.5 mL contains:

<table>
<tr><th>Ingredient</th><th>Quantity / dose Strength: 25 µg</th><th>Quantity / dose Strength: 50 µg</th><th>Quantity / dose Strength: 100 µg</th></tr>
<tr><td>Inactivated Chikungunya Antigen[#]</td><td>25 µg</td><td>50 µg</td><td>100 µg</td></tr>
<tr><td>Al^{3+} as Aluminum hydroxide</td><td>NMT 1.25 mg</td><td>NMT 1.25 mg</td><td>NMT 1.25 mg</td></tr>
<tr><td>Oil in water emulsion adjuvant (ZyADs)*</td><td>0.25 ml</td><td>0.25 ml</td><td>0.25 ml</td></tr>
<tr><td>Polysorbate 80</td><td>0.02% (w/v)</td><td>0.02% (w/v)</td><td>0.02% (w/v)</td></tr>
<tr><td>Phosphate Buffer Saline</td><td>q.s.</td><td>q.s.</td><td>q.s.</td></tr>
</table>

[#]Chikunguniya Virus propagated on Vero cells and inactivated by formaldehyde.
* A squalene-based emulsion adjuvant</td></tr>
<tr><td>Indication(s):</td><td>For active immunization against chikungunya virus infection.</td></tr>
</table>

Details of clinical trial sites:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1.	Zydus Lifesciences Ltd., Survey No. 396/403, Sarkhej-Bavla National Highway No. 8A Moraiya, Ahmedabad - 382213, Gujarat India.	Riddhi Medical Nursing Home Institutional Ethics Committee, Riddhi Medical Nursing Home, A/101 Jalaram Plaza, Jawahar Chowk, Maninagar, Ahmedabad Gujarat - 380008 Registration No.: ECR/886/Inst/GJ/2016/RR-24	Dr. Krunal Prajapati (M.D. Pharmacology)

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

I. The proposed clinical trial should be conducted as per protocol titled "A prospective, randomized, double-blind, placebo-controlled, Phase I clinical trial to evaluate the safety, tolerability and immunogenicity of Chikungunya vaccine candidate of M/s. Zydus Lifesciences Ltd. in healthy human participants" (Protocol No.: ZYCHIK 1001, Version 03 dated 30.01.2026).

II. The firm will submit interim analysis report of immunogenicity data till 28 days after 2nd dose and safety data till 84 days after 2nd dose along with the DSMB report to CDSCO before planning for conduct of Phase II clinical trial.

III. Lethal dose challenge study in relevant animal model including non-human primates for confirmation of human protective dose.

IV. Developmental and reproductive toxicity (DART) study.

V. Immunogenicity data for confirmation of protective dose.

VI. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions and shall have on-going stability programme to ascertain that the available long term stability data cover the entire duration of clinical trial.

VII. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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