File No: BIO/CT/23/000027
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 Cadila Pharmaceuticals Limited, 1389, Trasad Road, Dholka, Ahmedabad, Gujarat (India) - 382225 to conduct Phase-I clinical trial of the new drug or investigational new drug as per Protocol No.: CRSC23001, Version no.: 02 dated 16.06.2023 in the below mentioned clinical trial sites.

CT No.: CT- 02/2024

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.

RAJEEV SINGH RAGHUVANSHI

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

Place: New Delhi
Date:

Annexure: Details of New Drug or Investigational New Drug:

<table>
<tr><td>Name of the new drug or investigational new drug:</td><td>Varicella Zoster Virus (VZV) Vaccine</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Sterile Lyophilized Vaccine for Intramuscular Injection.

Varicella Zoster Virus (VZV) Vaccine 50 µg/0.5 mL is presented as a combination of 2 vials:
i. One vial containing the Lyophilized powder (Antigen) – 50 µg/vial
ii. One vial containing the reconstitution solution (Adjuvant) – 1 ml Adjuvant/vial

The antigen vial must be reconstituted with reconstitution (adjuvant) solution prior to administration.</td></tr>
<tr><td>Composition:</td><td>i. Varicella Zoster Virus (VZV) Vaccine 50 µg dose /Vial contains:

<table>
<tr><th>Ingredients</th><th>Quantity</th></tr>
<tr><td>Varicella-Zoster gE protein</td><td>50 µg</td></tr>
<tr><td>Disodium Hydrogen Phosphate Anhydrous</td><td>1.505 mg</td></tr>
<tr><td>Sodium dihydrogen phosphate Monohydrate</td><td>0.257 mg</td></tr>
<tr><td>Sodium Chloride</td><td>14.61 mg</td></tr>
<tr><td>Sucrose</td><td>30 mg</td></tr>
<tr><td>Histidine</td><td>5 mM</td></tr>
<tr><td>Polysorbate - 80</td><td>0.5 mg</td></tr>
</table>
ii. Each Reconstitution solution (Adjuvant) vial contains:
<table>
<tr><th>Content</th><th>Quantity</th></tr>
<tr><td>Alum</td><td>1000 µg</td></tr>
<tr><td>Water for Injection</td><td>q.s. 1 ml</td></tr>
</table></td></tr>
<tr><td>Indication(s):</td><td>For active immunization against varicella in healthy subjects.</td></tr>
</table>

Details of clinical trial site:

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Apollo Hospital International Ltd., Plot No. – 1a, GIDC Estate, Bhat, Ghandhinagar – 382428, Gujarat, India.	Institutional Ethics Committee-Clinical Studies, Apollo Hospitals International Ltd, Plot No.1a, GIDC Estate, Bhat, Gandhinagar (India) - 382428 India. [ECR/30/Inst/GJ/2013/RR-19]	Dr. Desai Maharshi Bipinchandra

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 "A randomized, open label clinical trial to evaluate the safety and immunogenicity of varicella-zoster virus (VZV) vaccine in healthy subjects [Protocol No.: CRSC23001, Version no.: 02 dated 16.06.2023].
II. The firm is required to constitute a DSMB to review the safety data.
III. Firm is required to submit Ethics Committee approval for Phase-I clinical trial.
IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions.
V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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