File No: BIO/CT/25/000034
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 permit M/s Reliance Life Sciences Pvt Ltd, Dhirubhai Ambani Life Sciences Centre, R-282, TTC area of MIDC, Thane Belapur road, Rabale, Navi Mumbai, Maharashtra(India)- 400701 Telephone No.: 02235338000 FAX: 02235338099 to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: RLS/VAC/2025/05 Version No. 1.0, Date 02.07.2025 in the below mentioned clinical trial sites.

**CT No.: CT- 04/2026**

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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(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>Purified Vero Cell Rabies Vaccine (PVRV) (Human) (R-VAC-002)</td></tr>
<tr><td>Therapeutic class:</td><td>Vaccine</td></tr>
<tr><td>Dosage form:</td><td>Freeze dried (Vial)</td></tr>
<tr><td>Composition:</td><td>Each freeze-dried vial contains:<br><br><table><tr><th>Ingredients</th><th>Quantity</th></tr><tr><td colspan="2">Active Ingredients</td></tr><tr><td>Rabies virus antigen (I.P.)</td><td>NLT 2.5 IU</td></tr><tr><td colspan="2">Inactive Ingredients</td></tr><tr><td>Human serum albumin (In House Specification)</td><td>3.5%</td></tr><tr><td>Maltose (In House Specification)</td><td>4.5%</td></tr><tr><td>Phosphate Buffer Saline(In House Specification)</td><td>q.s.</td></tr></table><br>Diluent: Ampoule containing 1ml Saline 0.3 % (w/v).</td></tr>
<tr><td>Presentation:</td><td>2R vials (USP EP Type-1 clear glass vial)</td></tr>
<tr><td>Indication(s):</td><td>Prevention of rabies in children and adults. It can be used before or after exposure, as a primary immunization or as a booster dose.</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. | Reliance Life Sciences Clinical Pharmacology Unit, Navi Mumbai Maharashtra, Reliance Life Sciences Pvt Ltd.,Dhirubhai Ambani Life Sciences Centre, B-22, Plot R-282, B22 building, TTC Area of MIDC, Rabale, Navi Mumbai, Maharashtra, India- 400701 Navi Mumbai Maharashtra- 400701 | Suraksha Ethics Committee, Asian Institute of medical science (AIMS), Plot P-72, Milap nagar, MIDC, Dombivli-421201, Dist: Thane, Maharashtra, India.<br><br>**(ECR/644/Inst/MH/2014/RR-20)** | Dr Sachin Kagane |

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 phase I clinical trial to evaluate safety of single dose of Purified Vero Cell Rabies Vaccine (PVRV) (Human) R-VAC-002 of Reliance Life Sciences Pvt. Ltd. in healthy human adult participants.”(Protocol No.: RLS/VAC/2025/05; Version1.0, Dated:02/Jul/2025).

II. The firm is required to constitute a DSMB to review the safety data.

III. The formulation intended to be used in the Phase I 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.

IV. Only CDL, Kasauli certified batches shall be used in the Phase I clinical trial.

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

Place: New Delhi
Date: