Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Mr Steve Nguyen
Associate Director Head of QA
Eurofins Advantar Laboratories Inc
5451 Oberlin Drive Suite 100
San Diego CA 92121
United States of America

TGA Reference: E21-209630

**Subject: Issue of GMP certificate MI-2024-CE-02770-1**

Dear Mr Nguyen,

Please find enclosed the GMP certificate for your manufacturing premises.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely,

Signed and authorised by

Emmett Broderick
Senior GMP Inspector
Manufacturing Quality Branch

01 May 2025

Contact: GMP@health.gov.au, Phone: 1800 020 653

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

# Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2024-CE-02770-1

**Issued to:**

Eurofins Advantar Laboratories Inc

**Manufacturing Site Address:**

5451 Oberlin Drive Suite 100
San Diego CA 92121
United States of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing manufacturers located outside Australia.

This certificate is issued based on a remote inspection of GMP compliance. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 04 to 05 February 2025, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 February 2022.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

**Issue Date:** **01 May 2025** **Expiry Date:** **5 August 2028**

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

# Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2024-CE-02770-1

**MANUFACTURING OPERATIONS**

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

| Manufacturing Type | Sterility | Dosage Form | Product Category | Manufacturing Step |
|---|---|---|---|---|
| Testing Laboratory | Sterile | Injections | Registered Therapeutic Good | Testing chemical and physical |

The following limitations are applicable to these manufacturing operations:

Restricted to chemical testing of solution injection vial Empaveli (ARTG 346216) and Syfovre (ARTG 404733). Both contain the active Pegcetacoplan.

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.
The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au