Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Mr Anjan Mittal
Vice President - Quality Assurance
Eurofins BioPharma Product Testing (US)
Eurofins Lancaster Laboratories, LLC
2425 New Holland Pike
Lancaster PA 17601
United States of America

TGA Reference: E19-525195

Subject: Issue of GMP certificate MI-2023-CE-12102-2

Dear Mr Mittal,

Please find enclosed the GMP certificate for your laboratory 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

Neale Baldwin
Senior GMP Inspector
Manufacturing Quality Branch

06 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-2023-CE-12102-2

Issued to:

Eurofins Lancaster Laboratories LLC

Manufacturing Site Address:

2425 New Holland Pike
Lancaster PA 17601
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.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 09 to 12 December 2024, 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: **06 May 2025** **Expiry Date:** **12 June 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

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Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-CE-12102-2

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 & Non Sterile	API - Not Defined	Not Applicable	Testing microbial
Testing Laboratory	Sterile & Non Sterile	API - Not Defined	Not Applicable	Testing biological
Testing Laboratory	Sterile & Non Sterile	API - Not Defined	Not Applicable	Testing chemical and physical
Testing Laboratory	Sterile	API - Not Defined	Not Applicable	Testing sterility
Testing Laboratory	Sterile & Non Sterile	API - Not Defined	Not Applicable	Testing Endotoxin
Testing Laboratory	Sterile & Non Sterile	API - Not Defined	Not Applicable	Testing Molecular PCR
Testing Laboratory	Sterile & Non Sterile	API - Not Defined	Not Applicable	Testing Virology
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing microbial
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing biological
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing chemical and physical
Testing Laboratory	Sterile	All Dosage Forms	Registered Therapeutic Good	Testing sterility
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing Endotoxin
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing Molecular PCR

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Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2023-CE-12102-2

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Testing Laboratory	Sterile & Non Sterile	All Dosage Forms	Registered Therapeutic Good	Testing Virology
Active Pharmaceutical Ingredient manufacture	Sterile & Non Sterile	API - Not Defined	Not Applicable	Manufacture and/or maintenance of master cell bank and/or working cell bank

The following limitations are applicable to these manufacturing operations:

No further conditions are applicable.

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