



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Evelyn Rodriguez
WuXi AppTec Inc
2540 Executive Drive
St Paul MN 55120
United States of America

TGA Reference: [2014/030189](#)

Subject: Issue of GMP certificate MI-2021-CE-13546-1

Dear Ms Rodriguez,

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

Alyce Maksoud
Senior GMP Inspector
Manufacturing Quality Branch

07 June 2024

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-2021-CE-13546-1

Issued to:

WuXi AppTec Inc

Manufacturing Site Address:

2540 Executive Drive
St Paul MN 55120
United States of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following Section 32EA(1) of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 24 to 26 October 2023, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products (2013).

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: 07 June 2024

Expiry Date: 26 April 2026

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.



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Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2021-CE-13546-1

MANUFACTURING OPERATIONS

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

Manufacturing Type	Manufacturing Step
Testing Laboratory - Blood Tissue Cellular	Testing biological

The following limitations are applicable to these manufacturing operations:

Testing biological is limited to testing of human tissue products for Osteoinduction.

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.