Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Ms. Jennifer Cheung
VP, Quality Assurance
WuXi Advanced Therapies Inc
400 Rouse Boulevard
Philadelphia Pennsylvania 19112 USA

TGA Reference: E21-321663

Subject: Issue of GMP certificate MI-2023-CE-14520-1

Dear Ms. Cheung,

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

Maurice Makdessi
Senior GMP Inspector
Manufacturing Quality Branch

29 November 2023

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-14520-1

Issued to:

WuXi Advanced Therapies Inc

Manufacturing Site Address:

400 Rouse Boulevard
Philadelphia Pennsylvania 19112
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 during COVID-19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 8 to 11 March 2022, 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 July 2018.

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: **29 November 2023** **Expiry Date:** **11 September 2024**

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-2023-CE-14520-1

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	Injection, intravenous infusion	Registered Therapeutic Good	Testing Adventitious Virus
Testing Laboratory	Sterile	Injection, intravenous infusion	Registered Therapeutic Good	Testing Mycoplasma
Testing Laboratory	Sterile	Injection, intravenous infusion	Registered Therapeutic Good	Testing *

The following limitations are applicable to these manufacturing operations:

*Testing here refers to testing for Minute Virus of Mouse and Characterisation Testing (Cell line)

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