Australian Government
Department of Health
Therapeutic Goods Administration

Mr Michael McCormick
V.P Quality Assurance and Regulatory Affairs
WuXi AppTec, Inc
4751 League Island Boulevard
Philadelphia Pennsylvania 19112
United States of America

Our Reference: E18-280337

Dear Mr McCormick,

Subject: Issue of GMP certificate MI-2018-CE-04632-1

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

Katherine Clark
Director – Licensing & Certification Section
Manufacturing Quality Branch

08 July 2019

Contact: gmp@tga.gov.au, phone +61 2 6221 6881 or fax +61 2 6232 8426

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2018-CE-04632-1

Issued to:

WuXi AppTec, Inc

Manufacturing Site Address:

4751 League Island Boulevard
Philadelphia Pennsylvania 19112
United States of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer of Active Pharmaceutical Ingredients (APIs) 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 API manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 20 to 22 March 2019, 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 January 2017.

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.

EXPIRY DATE: **22 May 2021**

ISSUE DATE: **08 July 2019**

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: 02 6232 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2018-CE-04632-1

MANUFACTURING OPERATIONS

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

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Active Pharmaceutical Ingredient manufacture	Sterile	API - Not Defined	Registered Therapeutic Good	Manufacture and/or maintenance of master cell bank and/or working cell bank
Active Pharmaceutical Ingredient manufacture	Non Sterile	API - Not Defined	Registered Therapeutic Good	Testing Mycoplasma
Testing Laboratory	Non Sterile	API - Not Defined	Registered Therapeutic Good	Testing Adventitious Virus
Testing Laboratory	Non Sterile	API - Not Defined	Registered Therapeutic Good	Testing biological

The following limitations are applicable to these manufacturing operations:

This certificate only authorises the manufacture, temporary storage under quarantine, testing and final release of sterile mammalian Master Cell Banks (MCB) and Working Cell banks (WCB). Biological testing of API is authorised for Assessment of Authenticity and Species Identity, Mycoplasma, General Virus Screens, Specific Virus Tests, Retroviruses, and Adventitious Viruses from Animal-Derived Raw Material.

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The authenticity of this Certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

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