台州市星明药业有限公司
TAIZHOU XINGMING PHARMACEUTICAL CO., LTD.

Statement on Clozapine TGA certificate

Subject to Clozapine TGA certificate MI-2017-CE-03755-1

We, Taizhou Xingming Pharmaceutical Co., Ltd., hereby declare that we were informed by our Australian sponsor Pfizer via email that they have extended the validity period of our Clozapine TGA GMP clearance (MI-2017-CE-03755-1) until 14 December 2021, and if no inspection scheduled till then , they will apply another extension.

Signature: _____

Name: Mr. Lu Jihong

Designation: Quality Deputy General Manager

Taizhou Xingming Pharmaceutical Co., Ltd.

中国浙江台州椒江区滨海路 89 号
No.89 Binhai Road, Jiaojiang District, Taizhou City, Zhejiang Province, P.R. China.

Tel: +86 57688582618, +86 57688582628
Fax: +86 576 8858 2603 Post code: 318000
Email: sales@xm-chem.com

20.149

Australian Government

Department of Health
Therapeutic Goods Administration

Mr Lu Jihong
Taizhou Xingming Pharmaceutical Co., Ltd.
No. 89 Binhai Road, Jiaojiang
Taizhou Zhejiang 318000
China – Peoples Republic of

Our Reference: 2014/024338

Dear Mr Lu Jihong,

Subject: Issue of GMP certificate MI-2017-CE-03755-1

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.

Issued as a photographic copy of a document, presented to me, mr. Cornelis van Ark, notary, residing at the municipal of West Maas en Waal, on the fifth of October two thousand and twenty.

Yours sincerely,

Signed and authorised by

Doreene Kohalmi
Senior Inspector
Manufacturing Quality Branch

1 March 2018

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-2017-CE-03755-1

Issued to:

Taizhou Xingming Pharmaceutical Co., Ltd.

Manufacturing Site Address:

No. 89 Binhai Road, Jiaojiang

Taizhou Zhejiang 318000 China - Peoples Republic of

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 11 to 14 December 2017, 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 - 15 January 2009.

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: 14 June 2021

ISSUE DATE: 1 March 2018

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

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GA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufac

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2017-CE-03755-1

...ture of APIs as

de Rechtspraak
Rechtbank Gelderland

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
   This public document
2. has been signed by **mr. C. van Ark**
3. acting in the capacity of notary at West Maas en Waal
4. bears the seal/stamp of aforesaid notary

Certified

5. in Arnhem
6. on 19-10-2020
7. by the registrar of the district court of Gelderland
8. no. 20-2278
9. Seal/stamp:
10. Signature:

T.J. van der Linden

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

of Active Pharmaceutical Ingredients (APIs)

Certificate Number:

MI-2017-CE-03755-1

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	Non Sterile	API - Not Defined	Registered Therapeutic Good	Active Pharmaceutical Ingredient manufacture

The following limitations are applicable to these manufacturing operations:

The manufacturer is restricted to the manufacture of clozapine active pharmaceutical ingredient excluding release for supply.

ACTIVE SUBSTANCES MANUFACTURED

Clozapine

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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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TGA Health Safety Regulation