



**APOSTILLE**

(Convention de La Haye du 5 octobre 1961)

1. Country **Australia**

This public document  
2. has been signed by **Matthew John Herbert Davis**  
3. acting in the capacity of **Lead Inspector**  
bears the seal/stamp of **Therapeutic Goods Administration  
Australia, Department Of Health And  
Ageing (TGA)**

Certified

at Canberra  
by **Kim Pepper**  
CHCH-UF-2497  
9. Seal/Stamp  
6. the 11th day of July, 2016  
Department of Foreign Affairs and Trade  
Canberra  
Australia

10. Signature

*K Pepper*



*This Apostille only certifies the authenticity of the signature (where applicable) and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued. This Apostille can be verified at <https://orao.dfat.gov.au/pages/verifyapostille.aspx>*



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Certificate of GMP Compliance of a Manufacturer

**Certificate Number:**

MI-2015-CE-04004-1

**Issued to:**

Jewim Pharmaceutical (Shandong) Co., Ltd.

**Manufacturing Site Address:**

Middle of Chuangye Main Street  
Taian High-Tech Industrial Development Zone  
Shandong Province 271000  
PEOPLES REPUBLIC OF CHINA

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 18 April 2016 to 21 April 2016, 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: 21 April 2019**

**ISSUE DATE: 30 June 2016**

Name and signature of an authorised person of the Competent Authority of Australia:

Signed:

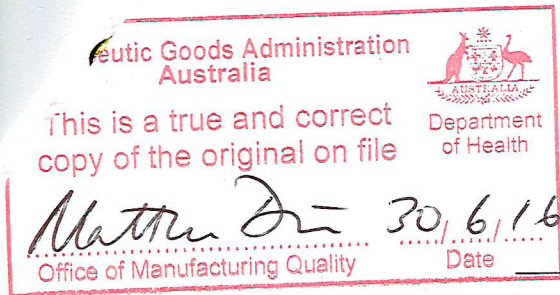
Matt Davis, Senior Inspector  
Manufacturing Quality Branch

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.  
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 8444 Fax: 02 6232 8605 Email: [info@tga.gov.au](mailto:info@tga.gov.au) [www.tga.gov.au](http://www.tga.gov.au)

**TGA** Health Safety  
Regulation





Department  
of Health



Australian Government

Department of Health  
Therapeutic Goods Administration

## Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2015-CE-04004-1

### 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
Medicine manufacture	Non Sterile	Inhalation	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Spray	Registered Therapeutic Good	Finished Product Manufacture

Name and signature of an authorised person of the Competent Authority of Australia:

Signed:

Matt Davis, Senior Inspector  
Manufacturing Quality Branch

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**TGA** Health Safety  
Regulation