



中华人民共和国
药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS
PEOPLE'S REPUBLIC OF CHINA

证书编号: SD20130100
Certificate No.

企业名称: 山东京卫制药有限公司
Manufacturer: Jewin Pharmaceutical (Shandong) Co., Ltd.

地址: 泰安高新技术产业开发区创业大街中段; *泰安高新技术产业开发区配天门大街
Address: Tai'an High-Tech Industrial Development Zone, Shandong Province; *Peitianmen Street, Tai'an High-Tech Industrial Development Zone, Shandong Province

认证范围: 气雾剂、喷雾剂(均含激素类), *片剂
Scope of Inspection: Aerosol And Spray(Both Including Hormones), *Tablets

经审查,符合中华人民共和国《药品生产质量管理规范》要求。
特发此证。

This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至 2018 年 07 月 17 日

This certificate remains valid until

发证机关:
Issued By



Date for Issuing 18/07/2013 2013 年 07 月 18 日

国家食品药品监督管理局制

PRINTED BY STATE FOOD AND DRUG ADMINISTRATION

公 证 书

(2013)泰岱宗证外字第 2495 号

申请人：山东京卫制药有限公司，登记注册地址泰安高新技术产业开发区创业大街中段。

法定代表人：李铁军，男，一九六四年七月二十六日出生，公民身份号码 110106196407260012。

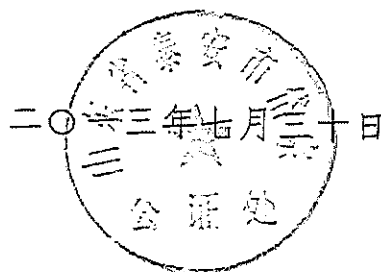
代理人：饶丽平，女，一九八二年十月二十日出生，公民身份号码 42092319821020094X。

公证事项：药品 GMP 证书

兹证明山东省食品药品监督管理局于二〇一三年七月十八日发给山东京卫制药有限公司的证书编号 SD20130100 号《中华人民共和国药品 GMP 证书》的原件与前面的复印件相符，原件属实。

中华人民共和国山东省泰安市岱宗公证处

公证员



1164344541



NOTARIAL CERTIFICATE

(2013)Taidaizong Zheng Wai Zi, No. 2495

Applicant: Jewim Pharmaceutical (Shandong) Co., Ltd.,
Registered Address Chuangye Street (Middle) , Taian Hi-tech
Industrial Development Zone.

Legal Representative: Li Tiejun , male, born on July 26,
1964, ID Card No. 110106196407260012.

Agent: Rao Liping, female, born on October 20, 1982, ID
Card No. 42092319821020094X.

Issue under notarization: Certificate of Good
Manufacturing Practices for Pharmaceutical Products

This is to certify that the foregoing copy of the Certificate
of Good Manufacturing Practices for Pharmaceutical Products
People's Republic of China issued to Jewim Pharmaceutical
(Shandong) Co., Ltd. by Shandong Food and Drug
Administration on July 18, 2013 conforms to the original, and
that the original document is authentic.

Daizong Notary Public Office
Taian City
Shandong Province
The People's Republic of China
Notary Public: Xiao Wen
July 30, 2013



认字第13284222-001号

兹证明前而文书上公证处的印章和公证
员肖文的签名（印章）属实。

中华人民共和国外交部
领事司 一等秘书
二〇一三年八月八日



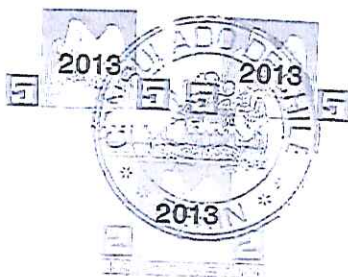
2161074

CONSULADO DE CHILE EN BEIJING
R.P. CHINA

EL CONSUL DE CHILE QUE SUSCRIBE CERTIFICA LA AUTENTICIDAD DE
LA FIRMA DE DON YANG YINGZI, PRIMER SECRETARIO DEL
DEPARTAMENTO CONSULAR LEGALIZACIONES DEL MINISTERIO DE
RELACIONES EXTERIORES DE LA R.P. CHINA.

NO. ACTUACION: 3518 ARANCEL ART. N° 4/10
DERECHOS US\$: 12.00 DIFERENCIA 10% US\$1.20
TOTAL PERCIBIDOS EN US\$ 13.20
PAGADO EN MONEDA DEL PAIS: ¥106.00
BEIJING, 12 DE AGOSTO DE 2013

FRANCISCO BARTOLUCCI
CONSUL

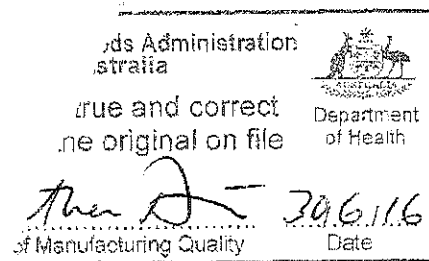


CONFIRMACION: Que esta fotocopia está
conforme con el documento que he tenido
a vista, compuesto de.....4.....fojas.

Santiago, 30-Agosto-2013.


JUAN FCO. ALAMOS OVEJERO
45° NOTARIO SUPLENTE SANTIAGO M/M





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 www.tga.gov.au

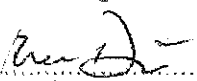
TGA Health Safety
Regulation

Therapeutic Goods Administration
Australia


Department
of Health

Check and correct
the original on file

Manufacturing Quality



30/6/16
Date



Australian Government
Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2015-CE-04004-1

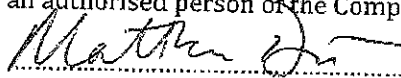
MANUFACTURING OPERATIONS

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

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.
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TGA Health Safety
Regulation



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country Australia

This public document
has been signed by
acting in the capacity of
bears the seal/stamp of

Matthew John Herbert Davis
Lead Inspector
Therapeutic Goods Administration
Australia, Department Of Health And
Ageing (TGA)

Certified

6. the 11th day of July, 2016

Department of Foreign Affairs and Trade
Canberra
Australia

at Canberra
by Kim Pepper

CHCH-OT-2491

9. Seal/Stamp

10. Signature

K



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
sent 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>