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: Jewim 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

药品监督管理局 17/07/2018

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420923198210200 94X。

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

二〇一三年七月二十日

I I 34344541

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

11 34344542

认字第13284222-001号

兹证明前面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. Nº 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

2013 2013 2013

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

Santiago, 30-Agosto-2013.

JUAN FCO. ALAMOS OVEJERO
45ª NOTARIO SUPLENTE SANTIAGO MM

El ministerio de Justicia de Chile Certifica la autenticidad de la firma de don

Santiago - 2 SEP 2013

VICTOR TRAVERSO MUÑOZ
Oficial Subrogante de Legalizaciones (S)

Legalizada en el Ministerio de Relaciones Exteriores de Chile
Firma del Señor

MIGUEL REYES VARGAS
Oficial de Legalizaciones

- 2 SE 2013

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

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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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

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country	**Australia**
This public document	
has been signed by	**Matthew John Herbert Davis**
acting in the capacity of	**Lead Inspector**
bears the seal/stamp of	**Therapeutic Goods Administration Australia, Department Of Health And Ageing (TGA)**
	Certified
Canberra	6. **the 11th day of July, 2016**
Kim Pepper	**Department of Foreign Affairs and Trade Canberra Australia**
CHCH-0T-2491	
9. Seal/Stamp	10. Signature

DEPT OF FOREIGN AFFAIRS AND TRADE * CANBERRA *

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