


190200018-001 1/3 ⑤
摩尔多瓦 EDC 002
2019/06/12

公 证 书

中华人民共和国
吉林省长春市信维公证处

CPP

吉林省食品药品监督管理局

JILIN PROVINCIAL FOOD AND DRUG ADMINISTRATION

药品证明书

Certificate of a Pharmaceutical Product

证书号: 2018011

No. of Certificate: 2018011

出口(发证)国: 中国

Exporting (certifying) country: China

进口(索取)国:

俄罗斯、乌克兰、乌兹别克斯坦、白俄罗斯、哈萨克斯坦、摩尔多瓦、阿塞拜疆、亚美尼亚、格鲁吉亚、新加坡、菲律宾、印度尼西亚、秘鲁、哥伦比亚、多米尼加共和国、乌拉圭、埃及、南非、约旦、巴西、巴拉圭、巴拿马、哥斯达黎加、萨尔瓦多、泰国、智利、蒙古

Importing (requesting) country:

Russia, Ukraine, Uzbekistan, Belarus, Kazakhstan, Moldova, Azerbaijan, The Republic of Armenia, Georgia, Singapore, Philippines, Indonesia, Peru, Columbia, Dominica Republic, Uruguay, Egypt, South Africa, Jordan, Brazil, Paraguay, Panama, Costa Rica, The Republic of El Salvador, Thailand, Chile, Mongolia.

1. 产品名称和剂型:

注射用重组人生长激素 2.5IU/瓶, 4.0IU/瓶, 4.5IU/瓶, 10IU/瓶, 12IU/瓶

Name and dosage form of product:

Recombinant Human Growth Hormone for Injection

2.5IU/vial, 4.0IU/vial, 4.5IU/vial, 10IU/vial, 12IU/vial

1.1 活性成分和数量/单位剂量:

重组人生长激素 2.5IU, 4.0IU, 4.5IU, 10IU, 12IU

Active ingredient(s) and amount(s) per unit dose:

Somatropin (IU) 2.5, 4.0, 4.5, 10, 12

非活性成分(辅料)/Excipients:

甘氨酸/ Glycine

蔗糖/ Sucrose

吐温-80/ Tween-80

甲硫氨酸/ Methionine

磷酸盐缓冲液/ Phosphate Buffer Solution

注射用水/ Water for Injection

1.2 本品是否在出口国获准上市使用? 是

Is this product licensed to be placed on the market for use in the exporting country? Yes

1.3 本品在出口国是否已经上市? 是

Is this product actually on the market in the exporting country? Yes

如 1.2 的回答是肯定的, 则继续 2A 部分并跳过 2B 部分;

If the answer to 1.2 is yes, continue with section 2A and omit section 2B;

如 1.2 的回答是否定的, 则跳过 2A 部分并继续 2B 部分。

If the answer to 1.2 is no, omit section 2A and continue with section 2B.

2A .1 药品批准文号和颁发日期:

国药准字 S20000001 (2.5IU) , 2015 年 8 月

国药准字 S20010032 (4.0IU) , 2015 年 8 月

国药准字 S10980101 (4.5IU) , 2015 年 8 月

国药准字 S10980102 (10IU) , 2015 年 8 月

国药准字 S20173003 (12IU) , 2017 年 5 月

Number of product license and date of issue:

China Drug Approval No. S20000001 (2.5IU) , August, 2015

China Drug Approval No. S20010032 (4.0IU) , August, 2015

China Drug Approval No. S10980101 (4.5IU) , August, 2015

China Drug Approval No. S10980102 (10IU) , August, 2015

China Drug Approval No. S20173003 (12IU) , May, 2017

2A.2 药品批准文号持有者 (名称和地址):

长春金赛药业股份有限公司

注册地址: 中国吉林省长春高新区天河街 72 号

Product-license holder (name and address):

GeneScience Pharmaceuticals Co., Ltd

Registered address: No.72, Tianhe Street, High-Tech Development Zone, Changchun,

Jilin Province, China

生产地址: 中国吉林省长春高新区越达路 1718 号

Manufacturing address: 1718 Yueda Road, High-Tech Development Zone,

Changchun, Jilin Province, China

2A.3 药品批准文号持有者的身份: a

Status of product license holder: a

(a) 药品（制剂）生产企业

(a) Manufactures the dosage form;

(b) 外包装和/或标签的由一个独立的公司生产，或

(b) Packages and/or labels a dosage form manufactured by an independent

company; or

(c) 以上均不是。

(c) Is involved in none of the above.

2A 3.1 对于类别 b 和 c 药品生产者的名称和地址： 不适用

For categories b and c the name and address of the manufacturer producing the dosage form is: Not applicable.

2A.4 是否附有药品证明文件？ 不适用

Is summary basis of approval appended? Not applicable

2A.5 所附的官方批准的产品信息是否齐全并和证书一致？ 是

Is the attached, officially approved product information complete and consonant with the license? Yes

2A.6 本证书的申请者与药品批准文号持有者（名称和地址）是否不同？ 否

Applicant for certificate, if different from license holder (name and address): No

2B.1 证书申请者（名称和地址）：

Applicant for certificate (name and address):

2B.2 申请者的地位：

Status of applicant:

2B.2.1 对于类别 b 和 c 药剂生产者的名称和地址是：

For categories b and c the name and address of the manufacturer producing the dosage form is:

2B.3 为什么缺少上市许可？

Why is marketing authorization lacking?

不需要/没有要求/在考虑中/被拒绝

not required/not requested/under consideration/refused:

2B.4 备注：

Remarks:

3. 发证当局是否安排对药剂生产厂家定期检查？ 是

Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes

如否，或未申请转至问题 4

(a) 药品（制剂）生产企业

(a) Manufactures the dosage form;

(b) 外包装和/或标签的由一个独立的公司生产，或

(b) Packages and/or labels a dosage form manufactured by an independent company; or

(c) 以上均不是。

(c) Is involved in none of the above.

2A.3.1 对于类别 b 和 c 药品生产者的名称和地址： 不适用

For categories b and c the name and address of the manufacturer producing the dosage form is: Not applicable.

2A.4 是否附有药品证明文件？ 不适用

Is summary basis of approval appended? Not applicable

2A.5 所附的官方批准的产品信息是否齐全并和证书一致？ 是

Is the attached, officially approved product information complete and consonant with the license? Yes

2A.6 本证书的申请者与药品批准文号持有者（名称和地址）是否不同？ 否

Applicant for certificate, if different from license holder (name and address): No

2B.1 证书申请者（名称和地址）：

Applicant for certificate (name and address):

2B.2 申请者的地位：

Status of applicant:

2B.2.1 对于类别 b 和 c 药剂生产者的名称和地址是：

For categories b and c the name and address of the manufacturer producing the dosage form is:

2B.3 为什么缺少上市许可？

Why is marketing authorization lacking?

不需要/没有要求/在考虑中/被拒绝

not required/not requested/under consideration/refused:

2B.4 备注：

Remarks:

3. 发证当局是否安排对药剂生产厂家定期检查？ 是

Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes

如否，或未申请转至问题 4

If no, or not applicable proceed to question 4

3.1 定期检查的周期（年）：每年

Periodicity of routine inspections (years): Annual

3.2 是否检查过本剂型的生产？ 是

Has the manufacture of this type of dosage form been inspected? Yes

3.3 生产设备及生产过程是否遵循世界卫生组织推荐的 GMP 要求？ 是

Do the facilities and operations conform to GMP as recommended by the World Health Organization? Yes

4. 认证当局是否对申请者递送的有关本品生产所有方面的资料感到满意？ 是

Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? Yes

如否，请解释：

If no, explain:

此证有效期为两年

Valid for two years

发证机构的地址：

吉林省食品药品监督管理局

中华人民共和国吉林省经济技术开发区湛江路 657 号

Address of certifying authority:

JILIN PROVINCIAL FOOD AND DRUG ADMINISTRATION

No. 657 Zhanjiang Road, Economic-Technological Development Zone, Changchun,

Jilin Province, China

签发人

Name of authorized person and Signature:

发证机构盖章和日期：2018.4.8

Stamp and date:

公 证 书

(2019)吉长信维证外民字第 4470 号

申请人：长春金赛药业股份有限公司，营业执照统一社会信用代码：91220101244976237H，住所：长春高新开发区天河街 72 号。

法定代表人：马骥，男，一九六五年四月二十一日出生，公民身份号码：220104196504215013。

代理人：牟振北，男，一九八七年九月十四日出生，公民身份号码：220204198709145412。

公证事项：药品证明书

兹证明吉林省食品药品监督管理局于二〇一八年四月八日发给长春金赛药业股份有限公司的《药品证明书》的原件与前面的复印件相符，原件属实。

中华人民共和国吉林省长春市信维公证处

公证员：

王楠

二〇一九年四月十六日

1187528305



NOTARIAL CERTIFICATE

(Translation)

(2019) J C X W Z W M Zi, No.4470

Applicant: Changchun GeneScience Pharmaceutical Co., Ltd.
(Former Name: Changchun GeneScience Pharmaceutical Co., Ltd.),
Business License Unified Social Credit Code:
91220101244976237H, Address: 72, Tianhe Street, Changchun
High-tech Development Zone.

Legal Representative: Ma Ji, male, born on April 21, 1965,
ID Card No. 220104196504215013.

Agent: Mu Zhenbei, male, born on Sep.14, 1987, ID Card No.
220204198709145412.

Issue under notarization: CERTIFICATE OF A PHARMACEUTICAL
PRODUCT

This is to certify that the original of CERTIFICATE OF A
PHARMACEUTICAL PRODUCT issued by JILIN PROVINCIAL FOOD AND
DRUG ADMINISTRATION on April 8, 2018 conforms to the foregoing
copy, and that the original document is authentic.

Notary: Wang Nan

Xinwei Notary Public Office of
Changchun City, Jilin Province
The People's Republic of China
April 16, 2019

1187605631



认字第190200018-001号

兹证明前面文书上公证处的印章和公证员王楠的签名（印章）属实。



中华人民共和国外交部
领事司一等秘书
二〇一九年五月二十七日

杨楠



The Embassy of the Republic of Moldova
to the People's Republic of China
authenticates the preceding signature and stamp
no. 289
29 05 2019
Rusu Alexandrina First Secretary
Name, surname
Position
The Embassy of the Republic of Moldova
is not responsible for the content of the document

