

Certificate of Pharmaceutical Product

药品说明书

This certificate conforms to the format recommended by the World Health Organization

此证书符合世界卫生组织（WHO）推荐的格式

No. of Certificate: CoPP-KL-202401

证书号: CoPP-KL-202401

Exporting (certifying country): P. R. China

出口国（提供证明的国家）: 中华人民共和国

Importing (requesting country): Moldova

进口国（提出要求的国家）: 摩尔多瓦

1. Name and dosage form of the product: Paclitaxel for Injection (Albumin Bound), powder for dispersion for infusion

1. 产品的名称和剂型: 注射用紫杉醇（白蛋白结合型），注射剂

1.1 Active ingredient(s) and amount(s) per unit dose: Paclitaxel 100mg

1.1 活性成分（原料药）和单位剂量: 紫杉醇 100mg

For complete composition including excipients: Each vial contains 100 mg of Paclitaxel and about 900 mg of Human Albumin

包括辅料在内的完整处方组成: 每瓶含紫杉醇 100mg 及人血白蛋白约 900mg

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

1.2 这一产品是否获得许可可在出口国市场上使用? 是

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

1.3 这一产品是否已经在出口国市场上使用? 是

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

如果对问题 1.2 的回答是肯定的，继续填写 2A 部分，省略 2B 部分。

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

如果对问题 1.2 的回答是否定的，省略 2A 部分，继续填写 2B 部分:

2.A.1. Number of product licence and date of issue:

2.A.1. 产品许可证的编号和签发日期:

GYZZ H20203443 Aug. 17, 2020

国药准字 H20203443 2020 年 8 月 17 日

2.A.2. Product licence holder (name and address):

2.A.2. 产品许可证持有人（名称和地址）:

Hunan Kelun Pharmaceutical Co., Ltd.

Site address: Kangwang Industrial Park, Yueyang Economic and Technological Development Zone, Hunan Province, P. R. China

湖南科伦制药有限公司; 生产地址: 湖南省岳阳经济技术开发区康王工业园

2.A.3. Status of product licence holder: (a/b/c) a. manufactures the dosage form

2.A.3. 产品许可证持有人的状况 (a/b/c) a. 生产者本人

a: manufactures the dosage form;

b: packages and/or labels a dosage form manufactured by an independent company; or

c: is involved in none of the above.

a: 生产者本人 b: 包装或贴标签的其他公司 c: 非 a 和 b 的其他公司

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is: /

2.A.3.1. 对于类别 b 和 c, 生产该制剂产品的厂家名称和地址是: /

2.A.4. Is a summary basis for approval appended? No

2.A.4. 是否附上了申报审批的综述材料? 否

2.A.5. Is the attached, officially approved product information complete and consonant with the licence? Not applicable

2.A.5. 所附的经过官方批准的产品信息是否完整并与许可证上的信息一致? 不适用

2.A.6. Applicant for certificate, if different from licence holder (name and address): /

2.A.6. 证书申请人（名称和地址），如果与许可证持有人不同： /

2.B.1. Applicant for certificate (name and address): OMIT

2.B.1. 证书申请人（名称和地址）：省略

2.B.2. Status of applicant: (Key in appropriate category as defined in footnote): Not applicable

2.B.2. 申请人的状况：不适用

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is: Not applicable

2.B.2.1. 对于类别 b 和 c，生产该制剂产品的厂家名称和地址是：不适用

2.B.3. Why is marketing authorization lacking? Not applicable

2.B.3. 为什么缺少上市许可？不适用

2.B.4. Remarks: Not applicable

2.B.4. 备注：不适用

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

Yes

3. 发证的监管部门是否安排对生产该制剂产品的工厂进行定期的现场检查？ 是

If not or not applicable, proceed to question 4.

如果没有或者是不适用，继续回答问题 4。

3.1. Periodicity of routine inspections (years): Half a year

3.1 常规检查的周期（几年）：半年

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

3.2 此类剂型的生产是否被检查过？ 是

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

3.3 生产厂家的各种设施和操作是否符合药品 GMP？ 是

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product:

Yes

4. 申请人提交的信息是否在产品生产的所有方面满足了发证机构的要求？ 是

If no, explain:

如果“否”，请给出解释：

This certificate remains valid for two years.

证书有效期两年。

Address of certifying authority:

Yueyang Market Supervision Administration:

No. 72 Qingnian Middle Road, Yueyang City, Hunan Province, P. R. China 414000

发证机构地址：

岳阳市市场监督管理局

中国湖南省岳阳市青年中路 72 号 414000

签字：Signature: _____

电话：Telephone number: +86 730 8843703

签章与日期：Stamp and date: _____

传真：Fax number: +86 730 8852890

