

## Certificate of a Pharmaceutical Product

### 药 品 证 明 书

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

该证书符合世界卫生组织（WHO）推荐的格式。

No. of Certificate: 20180396

证书号: 20180396

Exporting (certifying) Country: China

出口国: 中国

Importing (requesting) country: Democratic Republic of the Congo, Philippines, Yemen, Iraq, Venezuela, Uzbekistan

进口国: 刚果(金)、菲律宾、也门、伊拉克、委内瑞拉、乌兹别克斯坦

1. Name and Dosages form of product : Sodium Lactate Ringer's Injection-500ml

药品名称与剂量: 乳酸钠林格注射液-500ml

Active ingredient(s) and amount(s) per unit dose : Sodium Lactate 1.6g, Sodium Chloride 3.0g, Potassium Chloride 0.2g,

Calcium Chloride Dihydrate 0.135g

有效成分与剂量: 乳酸钠 1.6g, 氯化钠 3.0g, 氯化钾 0.2g, 氯化钙 0.135g

1.1 For complete composition including excipients : None

包括非活性成分在内的配方: 无

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

该药品在出口国是否允许投放市场? 是

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

该药品在出口国是否已实际投放市场? 是

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

若 1.2 的答案为是,请继续 2A。

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

若 1.2 的答案为否,请继续 2B。

2A.1 Number of product licence (AMM) and date of issue: GUOYAOZHUNZIH20044961 Date of issue : 2015.08.03

该药品批准文号和签发日期: 国药准字 H20044961 发证日期: 2015.08.03

2A.2 Product-licence holder(name and address): Shijiazhuang No.4 Pharmaceutical Co., Ltd. No. 288, Zhujiang Road, High-tech Industrial Development Zone, Shijiazhuang Yangzi Road, Economic & Technological Development Zone, Shijiazhuang City, Hebei Province

药品生产许可证的持有人(名称和地址): 石家庄四药有限公司石家庄高新技术开发区珠江大道 288 号石家庄经济技术开发区扬子路

2A.3 Status of product-licence holder: manufactures the dosage form

药品生产许可证的持有人的性质: 生产者本人

a: manufactures the dosage form

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

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

2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are: NOT APPLICABLE

如属情况 b 或 c, 药品实际生产者: 不适用

2A.4 Is summary Basis of Approval appended? No

是否附有审批的文件摘要? 否

2A.5 Is the attached, officially approved product information complete and consonant with the license? NOT APPLICABLE

所附的官方审批信息与许可证是否一致? 不适用

2A.6 Applicant for certificate, if different from licence holder (name and address): NOT APPLICABLE

证明书申请人(名称和地址)如与生产许可证的持有人不一致: 不适用

2B.1 Applicant for certificate (name and address): NOT APPLICABLE

证明书申请人(名称和地址): 名称: 不适用



No. of Certificate : 20180396

证书号: 20180396

地址: 不适用

2B.2 Status of applicant: a/b/c NOT APPLICABLE

申请人性质: (见 2A.3) 不适用

2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form are: NOT APPLICABLE

对于上题中 b 或 c 选项, 生产制剂产品的公司名称及地址: 不适用

2B.3 Why is the marketing authorization lacking? not required/not requested/under consideration/refused NOT APPLICABLE

为何缺少销售许可? 不适用

2B.4 Remarks: NOT APPLICABLE

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

证明当局是否对该药品的实际生产企业进行定期检查?是

If no or not applicable proceed to question 4.

若答案为不是或不适用,请继续 4

3.1 Periodicity of routine inspections(years): ONE

定期检查的周期: 一年

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

该药品的生产是否已经检查? 是

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

生产程序与设施是否与 WHO 推荐的报 GMP 一致?是

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? NOT APPLICABLE

If no, explain: \_\_\_\_\_

申请人所提供信息是否满足证明当局的要求?不适用

This certificate remains valid until: 2020-06-19

证书的有效期至: 2020-06-19

Address of certifying authority:

Hebei Province Food & Drug Administration

No. 391 Hongqi Street, Shijiazhuang, P.R. of China

证明当局的地址: 河北省食品药品监督管理局

河北省石家庄市红旗大街 391



签字: Signature

电话: Telephone number: 0086-311-83720090

签章与日期: Stamp and date: 2018 年 06 月 19 日

传真: Fax number: 0086-311-83720090

