

中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

药品出口销售证明

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

(未在中国注册药品)

(Product Unregistered in China)

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。

证书编号 (Certificate No.)	中文：苏 20210188
	英文：JS20210188
进口国/地区(提出要求的国家/地区) Importing Country /Region (Requesting Country /Region)	中文：埃及, 澳大利亚, 巴基斯坦, 韩国, 马来西亚, 蒙古, 孟加拉国, 日本, 泰国, 土耳其, 新加坡, 印度, 印度尼西亚, 越南
	英文：Egypt, Australia, Pakistan, Korea, Malaysia, Mongolia, Bangladesh, Japan, Thailand, Turkey, Singapore, India, Indonesia, Vietnam
产品名称与剂型 (Name and Dosages Form of the Product)	中文：杆菌肽锌 原料药
	英文：Bacitracin Zinc API
商品名 Trade Name	中文：无
	英文：none
活性成分与规格[不对外公开] Active Ingredient(s) and Strength [Not disclosed to the public]	中文：杆菌肽锌 原料药
	英文：Bacitracin Zinc API
包括辅料在内的完整处方组成 (可附表)[不对外公开] For complete composition including excipients, see attached [Not disclosed to the public]	中文：无
	英文：none



<p>该药品是否获得许可在中国市场上使用 Is this product licensed to be placed on the market for use in China</p>	<p>否 (No) (<input checked="" type="checkbox"/>)</p>	
<p>药品生产企业 (名称和地址) Manufacturer (name and address)</p>	<p>名称 Name</p>	<p>中文: 江苏九阳生物制药有限公司</p>
	<p>名称 Name</p>	<p>英文: Joyang Laboratories</p>
	<p>地址 Address</p>	<p>中文: 射阳经济开发区海都北路 9 号</p>
		<p>英文: No.9 Haidu North Road, Sheyang Economic Development Zone</p>
<p>未在中国注册的理由 Why is the product not registered in China</p>	<p>产品专门用于治疗中国以外地域的疾病 () The product has been developed exclusively for the treatment of diseases outside of China 产品处方组成有调整, 以改进在中国以外地域特定条件下的稳定性 () The product has been reformulated with a view to improving its stability under specific conditions outside of China 产品处方组成有调整, 以除去在进口国未被批准的辅料 () The product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the importing country 受专利权限制 () Restricted by patents 其他原因 (中英文) Any other reason (Chinese and English) 产品不在国内销售 The product is not sold in China</p>	
<p>证明当局是否对该药品的实际生产企业进行定期检查 Does the certifying authority arrange for periodic inspections of the manufacturing plant in which the dosage form is produced</p>	<p>是 (Yes) (<input checked="" type="checkbox"/>)</p>	
<p>定期检查的周期 Periodicity of routine inspections (years)</p>	<p>1</p>	



生产设备和操作是否符合中国药品生产质量管理规范的要求 Do the facilities and operations conform to the requirements of Chinese GMP	是 (Yes) (√)		
兹证明上述产品未在中国注册，尚未进入中国市场。该产品出口不受限制。 This is to certify that the above product(s) is not registered in China and not authorized to be placed in China. The exportation of the product(s) is not restricted.			
证明的有效期至 This certificate remain valid until	2023-03-17		
证明当局 Certifying authority	名称 Name	中文：江苏省药品监督管理局	
		英文：Jiangsu Drug Administration	
	地址 Address	中文：江苏省南京市鼓楼街 5 号	
		英文：No.5 Gulou Street, Nanjing City, Jiangsu Province	
	电话 Telephone number	025-83209367	
	传真 Fax	025-83273702	
	签字 Signature		
	签章与日期 Stamp and date	2021-03-18 (09)	

