



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
(已在中国批准上市药品)

(Pharmaceutical Product Approved in China)

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

该证明符合世界卫生组织(WHO)推荐的格式。

证书编号 Certificate No.	中文: 苏 20230148 号	
	英文: No.Jiangsu20230148	
进口国/地区(提出要求的国家/地区)[不对外公开] Importing Country /Region (Requesting Country /Region)[Not disclosed to the public]	中文: 印度尼西亚, 墨西哥	
	英文: Indonesia, Mexico	
产品名称与剂型 Name and Dosages Form of the Product	中文: 米诺地尔 不适用	
	英文: Minoxidil 不适用	
商品名 Trade Name	中文: 米诺地尔	
	英文: Minoxidil	
活性成分与规格[不对外公开] Active Ingredient(s) and Strength[Not disclosed to the public]	中文: 不适用 不适用	
	英文: 不适用 不适用	
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: 不适用	
	英文: 不适用	
该药品规格是否获得许可在中国市场上使用 Is this product strength licensed to be placed on the market for use in China	是 (Yes)	
该药品规格是否已经在中国国市场上使用 Is this product strength actually on the market in China	是 (Yes)	
产品批准文号(原料药备案号)及批准(备案)时间 Number of product license (DMF number) and date of issue	中文: Y20200000808 2022-10-25	
	英文: Y20200000808 October 25, 2022	
药品生产企业或者药品上市许可持有人(名称和地址) Manufacturer or Product-license holder(name and address)	名称 Name	中文: 常州金晟制药厂 英文: Changzhou Golden Bright Pharmaceutical Factory
	地址 Address	中文: 江苏省常州市金坛区金城镇庄城集镇 678 号 英文: No.678, Zhuangcheng, Jincheng Town, Jintan, Changzhou, Jiangsu Province, China
如果药品上市许可持有人不是生产者, 药品实际生产者是	生产者 Manufacturer	中文: / 英文: /

If the license holder is not the manufacturer, the name and address of the manufacturer producing the dosage form is	地址 Address	中文: / 英文: /
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	是 (Yes)	
定期检查的周期 (年) Periodicity of routine inspections (years)	5	
此类剂型的生产是否检查过 Has the manufacture of this type of dosage form been inspected	是 (Yes)	
生产设备和操作是否符合 WHO 推荐的药品生产质量管理规范 Do the facilities and operations conform to GMP as recommended by the World Health Organization	是 (Yes)	
申请人所提供的信息是否满足证明当局的要求 Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product	是 (Yes)	
兹证明上述产品符合中华人民共和国有关标准, 已在中国注册, 准许在中国市场销售。该产品出口不受限制。 This is to certify that the above product(s) comply with the relevant standards of the P. R. China, have been registered and authorized to be sold in China. The exportation of the product(s) is not restricted.		
证明的有效有效期至 This certificate remain valid until	2025-04-20	
证明当局 Certifying authority	名称 Name	中文: 江苏省药品监督管理局 英文: Jiangsu Medical Products 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, P.R. China
	电话 Telephone number	025-83209373
	传真 Fax	025-83278888
	签字 Signature	
	签章与日期 Stamp and date	2023-04-21