



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: 鲁20236093号	
	英文: No. Shandong20236093	
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: 摩尔多瓦; 伊拉克; 智利; 多米尼加; 危地马拉; 洪都拉斯; 尼加拉瓜; 哥斯达黎加; 巴拿马; 委内瑞拉; 玻利维亚; 萨尔瓦多; 毛里塔尼亚; 乍得; 也门; 喀麦隆; 多哥; 贝宁; 加纳; 乌干达; 坦桑尼亚; 马达加斯加; 津巴布韦; 乌里; 布基纳法索; 埃塞俄比亚; 巴拉圭; 巴基斯坦; 乌兹别克斯坦; 土库曼斯坦; 塔吉克斯坦; 哈萨克斯坦; 蒙古; 阿塞拜疆; 缅甸; 老挝; 柬埔寨; 菲律宾;	
	英文: Moldova; Iraq; Chile; Dominican Republic; Guatemala; Honduras; Nicaragua; Costa Rica; Panama; Venezuela; Bolivia; El Salvador; Mauritania; Chad; Yemen; Cameroon; Togo; Benin; Ghana; Uganda; Tanzania; Madagascar; Zimbabwe; Malawi; Burkina Faso; Ethiopia; Paraguay; Pakistan; Uzbekistan; Turkmenistan; Tajikistan; Kazakhstan; Mongolia; Azerbaijan; Myanmar; Laos; Cambodia; Philippines	
产品名称与剂型 Name and Dosages Form of the Product	中文: 注射用磷酸氟达拉滨, 注射剂	
	英文: Fludarabine Phosphate for Injection, Lyophilized Powder for Injection	
商品名 Trade Name	中文: 不适用	
	英文: Not applicable	
活性成分与规格 [不对外公开] Active Ingredient(s) and Strength [Not disclosed to the public]	中文: 磷酸氟达拉滨, 50mg	
	英文: Fludarabine Phosphate, 50mg	
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: 每支含磷酸氟达拉滨50mg, 甘露醇50mg	
	英文: Each vial contains Fludarabine Phosphate 50mg, Mannitol 50mg	
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: 国药准字H20103645, 2020-08-07	
	英文: GYZZ H20103645, August 07th, 2020	
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: 辰欣药业股份有限公司 英文: Cisen Pharmaceutical Co., Ltd.
	地址: Address	中文: 中国山东省济宁市高新区同济科技工业园 英文: Tongji Tech-Industry Garden, Jining High&New Technology Ind. Development Zone, Jining, Shandong Province, China.
如果药品上市许可持有人不是生产者, 药品实际生产者是谁 If the license holder is not the manufacturer, the name and address of the manufacturer producing the dosage form is	生产者: Manufacturer	中文: 不适用 英文: Not applicable
	地址: Address	中文: 不适用 英文: Not applicable
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)	一年 One year	
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, 允许在中国市场销售。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.		
证明的有效期限至 This certificate remain valid until	2025-07-05 July 5th, 2025	
证明当局 Certifying authority	名称: Name	中文: 山东省药品监督管理局 英文: Shandong Provincial Medical Products Administration
	地址: Address	中文: 山东省济南市经十路16122号 英文: No. 16122, Jingshi Road, Jinan City, Shandong Province, P. R. China
	电话: Telephone number	0086 530 5699071
	传真: Fax	0086 530 5699075
	签字: Signature	赵恒
	签章与日期: Stamp and date	2023年07月06日 July 6th, 2023

