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中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce



证明书

CERTIFICATE

231100B0/061845

号码 No.

兹证明：所附文件的影印件与原件相符。

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China Council for the Promotion
of International Trade



授权签字:

Authorized
Signature:

Lyu Cuilian

日期: 2023年09月06日
(Date: Sep. 06, 2023)

证 询网址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>

河北省药品监督管理局
药品 GMP 符合性检查结果通知单

编号：冀化药符检 2023056

企业名称	河北天成药业股份有限公司		
生产地址	河北省沧州市经济技术开发区金光大街 18 号		
检查范围	片剂，颗粒剂（口服固体车间 口服固体生产线），注射剂（输液一车间 大容量注射剂 S ₃ 线；输液二车间 大容量注射剂 S ₅ 线和大容量注射剂 S ₆ 线）		
药品生产许可证号	冀 20150098	受理号	
检查类型	药品 GMP 周期性符合性检查		
检查时间	2023 年 4 月 25-28 日		
检查员	王晓琦、代红丽、李丽平		
结论	该企业通过此次药品 GMP 符合性检查		
附件	药品 GMP 符合性检查缺陷项目		
主送	河北天成药业股份有限公司		
抄报			
抄送			

河北省药品监督管理局

2023 年 6 月 19 日



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证明
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HEBEI MEDICAL PRODUCTS ADMINISTRATION

Notification of GMP Compliance

No.: HEBEIHUAYAOFUJIAN 2023056

Manufacturer	Hebei Tiancheng Pharmaceutical Co., Ltd.		
Manufacture Address	No. 18 Jinguang Street, Economic & Technological Development Zone, Cangzhou		
Scope of Inspection	Tablets, Granules (Oral Solid Preparations Workshop Oral Solid Preparations Production Line), Infusion (Infusion S3 Line, Infusion S5 Line and Infusion S6 Line)		
Pharmaceutical Production License Certificate	HEBEI 20150098	Receiving No. of Application	
Type of Inspection	Periodic Inspection of GMP Compliance		
Time of Inspection	25/04/2023 to 28/04/2023		
Inspector	Wang Xiaoqi, Dai Hongli, Li Liping		
Conclusion	Compliance		
Attachment	Deficiency items during drug GMP compliance inspection		
TO	Hebei Tiancheng Pharmaceutical Co., Ltd.		
CC			
CC			



HEBEI MEDICAL PRODUCTS ADMINISTRATION

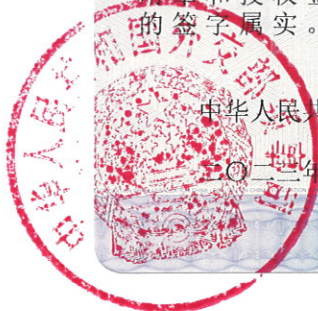
(Authority Stamp)

19/06/2023



认字第230366459-001号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章和授权签字人(吕翠连)的签字属实。



中华人民共和国外交部
领事司参赞
二〇二三年九月十二日



04225439

The Embassy of the Republic of Moldova
to the People's Republic of China
authenticates the preceding signature and stamp

no. 238
13 · 09 2023

Natalia Dima, First Secretary

Name, surname
Position

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is not responsible for the content of the document



01729592

中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书 CERTIFICATE



231100B0/031239

号码 No.

兹证明：所附中华人民共和国药品出口销售证明的影印件与原件相符。



THIS IS TO CERTIFY THAT: the annexed photostated copy of CERTIFICATE OF A PHARMACEUTICAL PRODUCT OF THE PEOPLE'S REPUBLIC OF CHINA is in conformity with the original.



China Council for the Promotion of International Trade



授权签字:

Authorized Signature: Lyu Cuilian

日期: 2023年05月16日
(Date: May. 16, 2023)

证明查询网址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>



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: 冀 20230003 号 英文: No.Hebei20230003	
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 英文: Moldova	
产品名称与剂型 Name and Dosages Form of the Product	中文: 甘露醇注射液,注射剂 英文: Mannitol Injection, Injectable	
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: 甘露醇 250ml:50g 英文: Mannitol250ml:50g	
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	
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 H13021754 2020 年 05 月 18 日 英文: GUOYAOZHUNZI H13021754 May 18 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: 河北天成药业股份有限公司 英文: Hebei Tiancheng Pharmaceutical Co., Ltd.
	地址 Address	中文: 河北省沧州经济技术开发区金光大街 18 号 英文: No.18, Jinguang Street, Economic & Technological Development Zone, Cangzhou, Hebei
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, 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.		
证明的有效期限至 This certificate remain valid until	2025 年 01 月 04 日 Jan 04, 2025	
证明当局 Certifying authority	名称 Name	中文: 河北省药品监督管理局 英文: Hebei Medical Products Administration
	地址 Address	中文: 河北省石家庄市红旗大街 391 号 英文: No.391 Hongqi Street, Shijiazhuang City, Hebei Province, P.R. China
	电话 Telephone number	0311-66635267
	传真 Fax	0311-66635264
	签字 Signature	
	签章与日期 Stamp and date	2023 年 01 月 05 日 Jan 05, 2023





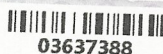
认字第230168383-004号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章和授权签字人(吕翠连)的签字属实。



中华人民共和国外交部
领事司二等秘书
二〇二三年五月十八日

张炳



03637388

The Embassy of the Republic of Moldova
to the People's Republic of China
authenticates the preceding signature and stamp
no. 115
"23" 05 2023
Noctalia Dima, First Secretary
Name, surname Position
The Embassy of the Republic of Moldova
is not responsible for the content of the document



Noctalia Dima

01729593

中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书 CERTIFICATE



号码 No. 231100B0/031238

兹证明：所附中华人民共和国药品出口销售证明的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of CERTIFICATE OF A PHARMACEUTICAL PRODUCT OF THE PEOPLE'S REPUBLIC OF CHINA is in conformity with the original.



China Council for the Promotion
of International Trade



授权签字:

Authorized
Signature: Lyu Cuilian

日期: 2023年05月16日
(Date: May. 16, 2023)



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的未注册规格)

(Unregistered Strength of the 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: 冀 20230009 号 英文: No Hebei20230009	
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 英文: Moldova	
产品名称与剂型 Name and Dosages Form of Product	中文: 甘露醇注射液,注射剂 英文: Mannitol Injection,Injectable	
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: 甘露醇 500ml: 100g 英文: Mannitol500ml: 100g	
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	
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	否 (No)	
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	否 (No)	
产品批准文号及批准时间 Number of product license and date of issue	中文: 国药准字 H13021754 2020年05月18日 英文: GUOYAOZHUNZI H13021754 May 18 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: 河北天成药业股份有限公司 英文: Hebei Tiancheng Pharmaceutical Co., Ltd.
	地址 Address	中文: 河北省沧州经济技术开发区金光大街 18 号 英文: No.18, Jinguang Street, Economic & Technological Development Zone, Cangzhou, Hebei
如果药品上市许可持有人不是生产者, 药品实际生产者 是 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)	
该规格未注册的理由 Why is the product strength (s) not registered in China	中英文说明 Specify in Chinese and English 进口国要求 Requested by Importing Country	
兹证明上述产品规格未在中国注册, 尚未进入中国市场。该产品规格出口不受限制。 This is to certify that the above product strength (s) is not registered in China and not authorized to be placed in China. The exportation of the product strength is not restricted		
证明的有效期至 This certificate remain valid until	2025年01月08日 Jan 08, 2025	
证明当局 Certifying authority	名称 Name	中文: 河北省药品监督管理局 英文: Hebei Medical Products Administration
	地址 Address	中文: 河北省石家庄市红旗大街 391 号 英文: No.391 Hongqi Street, Shijiazhuang City, Hebei Province, P.R. China
	电话 Telephone number	0311-66635267
	传真 Fax	0311-66635264
	签字 Signature	
	签章与日期 Stamp and date	2023年01月09日 Jan 09, 2023



认字第230168383-003号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章和授权签字人(吕翠莲)的签字属实。



中华人民共和国外交部
领事司二等秘书
二〇二三年五月十八日

张灼



03637387

The Embassy of the Republic of Moldova
to the People's Republic of China
authenticates the preceding signature and stamp

no. 114

"23" 05 2023

Natalia Dima, First Secretary

Name, surname
Position

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Handwritten signature