

# Fujian Kerui Pharmaceutical Co., Ltd.

YuanZai Industrial Area, HaiKou, EnQing, Fujian Province, China

## Certificate of Analysis

### CYCLOSPORINE EP

BATCH NUMBER	<u>110402(N)</u>	TEST DATE	<u>May.4.2011</u>
QUANTITY	<u>1000g</u>	MANUFACTURE DATE	<u>Apr.27.2011</u>
		EXPIRATION DATE	<u>Apr.26.2014</u>
TEST	SPECIFICATION	RESULT	
Characters	White powder practically insoluble in water freely soluble in ethanol and methylene chloride	<u>Conforms</u>	
Identification	Conforms to EP	<u>Conforms</u>	
Appearance of solution	Conforms to EP	<u>Conforms</u>	
Specific optical rotation	—185° to —193°	<u>—189°</u>	
Loss on drying	Not More Than 2.0%	<u>1.69%</u>	
Heavy metals	Not More Than 0.002%	<u>Conforms</u>	
Related compounds			
Individual	Not More Than 0.7%	<u>0.24%</u>	
Total	Not More Than 1.5%	<u>1.08%</u>	
Assay	98.5% to 101.5% calculate on the dried basis	<u>99.8%</u>	
Residual Solvents			
	Ethanol	Not More Than 0.1%	<u>Not Detected</u>
	Petroleum Ether	Not More Than 0.1%	<u>Not Detected</u>
	Acetone	Not More Than 0.1%	<u>Not Detected</u>
	Butyl Acetate	Not More Than 0.1%	<u>Not Detected</u>

Manufactured By: **Fujian Kerui Pharmaceutical Co., Ltd.**

FINAL BATCH DISPOSITION: Approved ( ) ☒ ☐

Analyst Date

*[Signature]*  
2012.8.18

Checker Date

*[Signature]*  
2012.8.18

By

Supervisor Date

*[Signature]* 2012.8.18

Version 2.01

01-13-2010



福建科瑞药业有限公司

**Fujian Kerui Pharmaceutical Co., Ltd.**

Yuanzai Industrial Area, Haikou, Fuqing, Fujian 350313, China  
Tel: 86-591-83476798 Fax: 86-591-83441193 E-mail: fjkerui@fjkerui.com

May 3, 2012

**Letter of Declaration of Manufacture  
Regarding the Risk of Transmitting Agents of  
Animal Spongiform Encephalopathies**

To Whom It May Concern:

We, Fujian Kerui Pharmaceutical Co., Ltd., hereby confirm that materials used in the manufacturing process of Cyclosporine are not derived from animals which are susceptible to TSE (cf. Ph. Eur. Chapter 5.2.8 Minimizing the risk of transmitting animal spongiform agents via medicinal products and the related general monograph no. 1483).

Sincerely yours,

Guiyun Chen

General Manager

Fujian Kerui Pharmaceutical Co., Ltd.



福建科瑞药业有限公司

**Fujian Kerui Pharmaceutical Co., Ltd.**

Yuanzai Industrial Area, Haikou, Fuzhou, Fujian 350313, China  
Tel: 86-591-8347-6798 Fax: 86-591-8344-1193 E-mail: fjkerui@fjkerui.com

May 3, 2012

**Letter of Declaration of Manufacture  
Without GMO**

To Whom It May Concern:

We, Fujian Kerui Pharmaceutical Co., Ltd., hereby confirm that our product Cyclosporine is a microbial fermentation product and no Genetically Modified Organisms have been used in the whole manufacturing process.

Sincerely yours,

Guiyun Chen

General Manager

Fujian Kerui Pharmaceutical Co., Ltd.

# 证明书

## CERTIFICATE



中国国际贸易促进委员会暨中国国际商会  
China Council for the Promotion of International Trade is China Chamber of International Commerce



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. 123500B0/01451

兹证明： 所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated  
copy of FILE is in conformity with the original.

CHINA COUNCIL FOR THE  
PROMOTION OF INTERNATIONAL  
TRADE IS CHINA CHAMBER OF  
INTERNATIONAL COMMERCE

China Council for the Promotion  
of International Trade

授权签字：

Authorized  
Signature : *Min Cong*

日期：2012 年04月26日

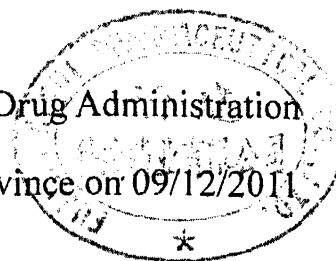
(Date: APR. 26, 2012)

## **NOTICE ABOUT PROLONGING THE VALID PERIOD OF CERTIFICATE OF GMP FOR PHARMACEUTICAL PRODUCTS**

Fujian Kerui Pharmaceutical Co.,Ltd

Your company has applied to prolong the valid period of the Certificate of Good Manufacturing Practices for Pharmaceutical Products covering bulk drugs (cyclosporine) and oral solutions. According to the requirements of Notice about Implementing and Complying With The Good Manufacturing Practices For Pharmaceutical Products (Amended In 2010) (Certificate No: 国食药监安(2011)101) and Notice about Prolonging The Valid Period of The Certificate Of Good Manufacturing Practices For Pharmaceutical Products (Certificate No: 食药监办安函(2011)269) issued by State Food and Drug Administration of P. R. China, the bulk drugs (cyclosporine) and oral solutions of your company meet the evaluation criteria for extending the expiration date of GMP Certificate and the Certificate of Good Manufacturing Practices for Pharmaceutical Products (Certificate No: 闽 H0096) will remain valid until 31/12/2012.

Issued by Food and Drug Administration  
of Fujian Province on 09/12/2011



中 华 人 民 共 和 国

# 药品GMP证书

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS  
PEOPLE'S REPUBLIC OF CHINA

证书编号: 闽 H0096  
Certificate No.

企业名称: 福建科瑞药业有限公司  
*Manufacturer:* Fujian Kerui Pharmaceutical Co., Ltd.

地 址: 福建省福清市海口元载工业村  
*Address:* Yuanzai Industrial Area, Haikou, Fuqing, Fujian

认证范围: 原料药(环孢素)、口服溶液剂、合剂、口服液  
*Scope of Inspection* Bulk Drugs (Cyclosporin), Oral Solutions, Mixture, Oral Solution

经审查,符合中华人民共和国《药品生产质量管理规范》要求。  
特发此证。

*This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.*

有效期至 2012 年 01 月 14 日

*This certificate remains valid until* 14/01/2012

发证机关:  
*Issued By*

*Date for Issuing* 15/01/2007

2007 年 01 月 15 日

国家食品药品监督管理局制

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