

# Fujian Kerui Pharmaceutical Co.,Ltd.

YuanZai Industrial Area,HaiKou,FuQing,FuJian Province 350313 China

## Certificate of Analysis

**CYCLOSPORINE EP**

Lote: 0091212

BATCH NUMBER

120604(N)

TEST DATE

Jul.06,2012

QUANTITY

1000g

MANUFACTURE DATE

Jul.1,2012

RETEST DATE

Jun.30,2015

TEST	SPECIFICATION	RESULT
Characters	White powder,practically insoluble in water,freely soluble in ethanol and methylene chloride.	Conforms
Identification	Conforms to EP	Conforms
Appearance of solution	Conforms to EP	Conforms
Specific optical rotation	—185°to —193°	—189°
loss on drying	Not More Than 2.0%	0.44%
Heavy metals	Not More Than 0.002%	Conforms
Related compounds		
Individual	Not More Than 0.7%	0.28%
Total	Not More Than 1.5%	0.89%
Assay	98.5% to 101.5% calculate on the dried basis	100.2%
Residual Solvents		
	<u>Ethanol</u>	Not More Than 0.1% 0.0011%
	<u>Petroleum Ether</u>	Not More Than 0.1% 0.0086%
	<u>Acetone</u>	Not More Than 0.1% 0.0032%
	<u>Butyl Acetate</u>	Not More Than 0.1% 0.0005%
Bacterial Endotoxins	Not More Than 0.84IU/mg	Conforms

Manufactured By: Fujian Kerui Pharmaceutical Co., Ltd.

FINAL BATCH DISPOSITION:

Approved (✓)



By:

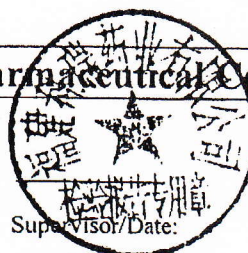
Analyst/Date:

2012年12月3日

Checker/Date:

2012年12月3日

Supervisor/Date:



2012年12月3日

Version 2.02

10-01-2012