

Lot: 091212

# Fujian Kerui Pharmaceutical Co., Ltd.

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

## Certificate of Analysis

**CYCLOSPORINE EP - Ed. 7.5**

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.	<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>0.44%</u>
Heavy metals	Not More Than 0.002%	<u>Conforms</u>
Related compounds		
Individual	Not More Than 0.7%	<u>0.28%</u>
Total	Not More Than 1.5%	<u>0.89%</u>
Assay	98.5% to 101.5% calculate on the dried basis	<u>100.2%</u>
Residual Solvents		
Ethanol	Not More Than 0.1%	<u>0.0011%</u>
Petroleum Ether	Not More Than 0.1%	<u>0.0086%</u>
Acetone	Not More Than 0.1%	<u>0.0032%</u>
Butyl Acetate	Not More Than 0.1%	<u>0.0005%</u>
Bacterial Endotoxins	Not More Than 0.84IU/mg	<u>Conforms</u>

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

FINAL BATCH DISPOSITION: Approved (✓) ☒

By:

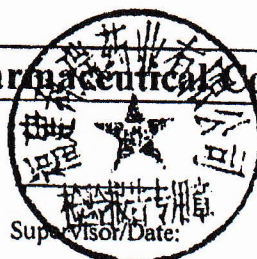
Analyst/Date:

Checker/Date:

Supervisor/Date:

林志丹  
2012年12月3日

李在松  
2012年12月3日



2012年12月3日

Version 2.02

10-01-2012