

Fujian Kerui Pharmaceutical Co.,Ltd.

YuanZai Industrial Area,HaiKou,FuQing,FuJian Province 350313 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		
	<u>Ethanol</u>	<u>Not More Than 0.1%</u>
	<u>Petroleum Ether</u>	<u>Not More Than 0.1%</u>
	<u>Acetone</u>	<u>Not More Than 0.1%</u>
	<u>Butyl Acetate</u>	<u>Not More Than 0.1%</u>
Bacterial Endotoxins	Not More Than 0.84IU/mg	<u>Conforms</u>

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


FINAL BATCH DISPOSITION: Approved (✓) ☒

By: 

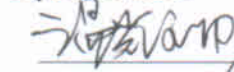
Analyst/Date:


2011年10月30日

Checker/Date:


2011年10月30日

Supervisor/Date:


2011年10月30日