

Lot: C081013

Fujian Kerui Pharmaceutical Co.,Ltd.

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

Certificate of Analysis

CYCLOSPORINE EP

BATCH NUMBER	130201(N)	TEST DATE	Feb.27,2013
QUANTITY	1000g	MANUFACTURE DATE	Feb.22,2013
		RETEST DATE	Feb.21,2016
TEST	SPECIFICATION	RESULT	
Characters	White powder,practically insoluble in water,freely soluble in ethanol and methylene chloride.	Conforms	
Identification	A. Infrared absorption spectrophotometry.	Conforms	
	B. Examine the chromatograms obtained in the assay.	Conforms	
Appearance of solution	Conforms to EP	Conforms	
Specific optical rotation	—185°to —193°	—190°	
loss on drying	Not More Than 2.0%	0.18%	
Heavy metals	Not More Than 0.002%	Conforms	
Related compounds			
	Individual	0.24%	
	Total	1.19%	
Assay	98.5% to 101.5% calculate on the dried basis	99.2%	
Residual Solvents	Ethanol	Not More Than 0.1%	5ppm
	Petroleum Ether	Not More Than 0.1%	27ppm
	Acetone	Not More Than 0.1%	11ppm
	Butyl Acetate	Not More Than 0.1%	Not Detected
Bacterial Endotoxins	Not More Than 0.84IU/mg	Conforms	

Manufactured By: Fujian Kerui Pharmaceutical Co., Ltd.

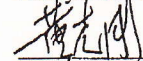
FINAL BATCH DISPOSITION: Approved (√) ☒

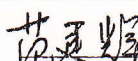
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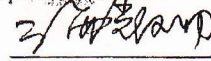
Analyst/Date:

Checker/Date:

Supervisor/Date:


2013年9月18日


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