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Fujian Kerui Pharmaceutical Co.,Ltd.

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

Certificate of Analysis

CYCLOSPORINE EP

BATCH NUMBER

140201(N)

TEST DATE

Mar.06,2014

QUANTITY

500g

MANUFACTURE DATE

Feb.28,2014

RETEST DATE

Feb.27,2017

| 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° | —192° |
| loss on drying | Not More Than 2.0% | 0.37% |
| Heavy metals | Not More Than 0.002% | Conforms |
| Related compounds | | |
| Individual | Not More Than 0.7% | 0.26% |
| Total | Not More Than 1.5% | 0.86% |
| Assay | 98.5% to 101.5% calculate on the dried basis | 100.1% |
| Residual Solvents | | |
| | Ethanol | Not More Than 0.1% |
| | Petroleum Ether | Not More Than 0.1% |
| | Acetone | Not More Than 0.1% |
| | Butyl Acetate | Not More Than 0.1% |
| | | 4ppm |
| | | 18ppm |
| | | 4ppm |
| | | Not Detected |
| Bacterial Endotoxins | Not More Than 0.84IU/mg | Conforms |

Manufactured By: Fujian Kerui Pharmaceutical Co., Ltd.

FINAL BATCH DISPOSITION: Approved (✓) ☒

By:

Analyst/Date:

Checker/Date:

Supervisor/Date:

2014年7月2日

2014年7月2日

2014年7月2日

Version 2.03

9-18-2013