



浙江瑞邦药业股份有限公司
ZHEJIANG RUIBANG LABORATORIES

CERTIFICATE OF ANALYSIS

Product **Ciclosporin**
Batch No. **10-170105** Quantity: **1kg**
Mfg. /Exp. Date **Jan 2017/ Jan 2019**
Specification **EP 9.0** Date: **Jan. 25, 2017**

Test	Specification	Results
Characters	White or almost white powder	White powder
Identification	Meet the requirements	Meet the requirements
Appearance of solution	Meet the requirements	Pass
Specific optical rotation (dried substance)	-185° ~ -193°	-189.0°
Loss on drying	Not More Than 2.0 %	0.36 %
Heavy metals	Not More Than 0.002 %	Conforms
Related substances		
1. Individual impurity	Not More Than 0.7 %	0.32%
2. Sum of all impurity	Not More Than 1.5 %	0.90 %
Residual Solvents		
Ethyl Acetate	Not More Than 5000ppm	6.6ppm
Ethanol	Not More Than 5000ppm	50.2 ppm
Acetone	Not More Than 5000ppm	5.1 ppm
Microbial limit test		
TAMC	Not More Than 1000cfu/g	<10 cfu/g
TYMC	Not More Than 100cfu/g	<10 cfu/g
Assay (on the dried basis)	97.0- 102.0 %	98.9 %

Conclusion **Comply with requirements of EP 9.0**

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