



# 湖北江民泰华化工有限公司

Hubei Taiho Chemical Co., Ltd

## Certificate of Analysis

Product name 品名	Rapmycin/Sirolimus 雷帕霉素/西罗莫司	CAS No. CAS 号	53123-88-9
Storage 贮存	Store in an airtight container 密闭避光贮存	Batch No. 批号	20210120
Specification No. 检验依据	Enterprise standard 企业标准	Report date 报告日期	2021/01/21
Test 检验项目	Specification 标准规定	Result 检验结果	
Description (外观性状)	white or off-white crystalline powder (白色或类白色结晶性粉末)	Complies (符合规定)	
Loss On Dry (干燥失重)	≤0.5%	0.19%	
Heavy metals (重金属)	<20ppm	Complies (符合规定)	
Individual Impurity (单杂)	≤1.5%	0.26%	
Residue on ignition (炽灼残渣)	≤0.2%	0.07%	
Total impurities (总杂)	≤2.0%	0.33%	
Isomer (异构体)	≤5.0%	2.71%	
Residual solvent (溶剂残留) ethanol (乙醇) ethyl acetate (乙酸乙酯) cyclohexane (环己烷) acetone (丙酮) ether (乙醚)	<200ppm <200ppm <200ppm <200ppm <200ppm	Complies (符合规定)	
Purity (纯度)	Calculated trans- and cis-isomers of Sirolimus on the dried basis NLT 98.5% 以干反式和顺式立体异构体计算, 不低于 98.5%	99.67%	
Conclusion (结论)	The product conforms to the enterprise specification. 本品符合企业标准		