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## 分析证明书

## CERTIFICATE OF ANALYSIS

Product name: Tacrolimus 他克莫司	
Batch no. 批号: 20221001	Quantity 数量: 11.240kg
Manuf. date 生产日期: 2022/10/04	Expiry date 有效期: 2024/10/03

Tests	Specifications	Results
Characters	White crystals or white crystalline powder	white crystalline powder
Identification	A Infrared absorption	Complies
	B The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay	Complies
Residue on ignition	NMT0.1%	0.005%
Optical rotation	-110° to -115°	-112°
Water	NMT4.0%	2.1%
<b>Organic impurities</b>		
Ascomycin 19-epimer	NMT0.1%	No detected
Ascomycin	NMT0.50%	No detected
Desmethyl tacrolimus	NMT0.1%	No detected
Tacrolimus 8-epimer	NMT0.15%	No detected
Tacrolimus 8-propyl analog	NMT0.15%	No detected
Any individual unspecified impurity	NMT0.1%	No detected
Total impurities	NMT1.0%	No detected
Assay (on the anhydrous and solvent-free basis)	98.0~102.0%	100.3%
<b>Residual solvent</b>		
Ethanol	NMT0.5%	No detected
Acetone	NMT0.5%	No detected
Ethyl acetate	NMT0.5%	0.01%
Isopropyl ether	NMT0.05%	0.005%
<b>Conclusion: Complies with current USP</b>		

复核人 Checker:

化验人 Analyst:

