

分析证明书

CERTIFICATE OF ANALYSIS

Product name: CYCLOSPORINE 环孢素 A EP	
Batch no. 批号: 20221027	Quantity 数量: 40kgs
Manuf. date 生产日期: 2022/11/05	Expiry date 有效期: 2025/11/04

ANALYSIS TEST 检验项目		SPECIFICATIONS 规格	RESULTS 结果
Appearance		White to almost white powder	white powder
Identification		IR:Conforms to the reference standard HPLC:The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with reference solution(a)	Conforms
Loss on drying		≤2.0%	0.3%
Specific optical rotation		-185° ~ -193°	-191°
Appearance of solution		Clarity:Should be clear	Conforms
		Colour:Not more intensely coloured than reference solution Y5,BY5 or R7	<R7
Related substances	Sun of impurities B and E	≤0.5%	0.3%
	I impurity G	≤0.4%	0.04%
	Any other impurity	≤0.3%	0.1%
	Total impurities	≤1.5%	0.6%
Residual solvent	Ethanol	≤5000ppm	94ppm
	Acetone	≤5000ppm	524ppm
	Ethyl acetate	≤5000ppm	27ppm
Microbial limits	TAMC	≤10 ³ cfu/g	<20cfu/g
	TYMC	≤10 ² cfu/g	<20cfu/g
	Escherichia Coli	Negative	Not detected
Bacterial endotoxins		<0.84IU/mg	Conforms
ASSAY(dried basis)		97.0%~102.0%	98.8%
CONCLUSION: Complies with EP10.5			

复核人 Checker:

化验人 Analyst:

