

分析证明书

CERTIFICATE OF ANALYSIS

Product name: Polymyxin B Sulfate(Non-Injection)硫酸多粘菌素 B	
Batch no. 批号: 20221003	Quantity 数量: 50kgs
Manuf. date 生产日期: 2022/10/15	Expiry date 有效期: 2024/10/15

Test items	Specification	Test results
Appearance	White or almost white, hygroscopic powder	White hygroscopic powder
Identification	HPLC	Conforms
	Color reaction with cupric sulfate solution	Conforms
	Sulfate reaction	Conforms
PH	5.0-7.5(5mg/ml)	5.86
Solubility	Freely soluble in water, slightly soluble in alcohol	Conforms
Loss on drying	≤7.0%	2.26%
Optical rotation	-78~-90(dried basis)	-82
Sulphated ash	≤0.75%	0.09%
Sulphate	15.5%~17.5%	16.06%
Heavy metals	≤20ppm	0.00
Related substance	Any impurity ≤3.0%	2.33%
	Total impurities ≤17.0%	11.49%
Microbiological examination	TAMC: ≤10cfu/g	Conforms
	TYMC: ≤10cfu/g	Conforms
	Staphylococcus aureus: undetected	Conforms
Particle size	NLT99% ≤30um by vol NLT 95% ≤20um by vol NLT 90% ≤15um by vol NLT 75% ≤10um by vol NLT 35% ≤5um by vol	Conforms
Purity -sum	>80.0%	88.22%
Purity-B3	Max6.0%	1.62%
Purity-BI-I	Max15.0%	6.05%
Assay	≥ 6000u/mg (Anhydrous)	7962u/mg
Sterility Tests	Sterility	Conforms
Conclusion	This product conforms with current USP and In-house specification	

复核人 Checker:

化验人 Analyst:

