



# 新昌县九信药业有限公司

## Xinchang JiuXin Pharmaceutical Co.,Ltd

### 质量检测报告书 Certificate of analysis

Product Name: 硫酸大观霉素 spectinomycin sulphate tetradrate

Packing: 1x 25Kg

Batch No.: YD1503003

Examined Basis: EP8 and in-house requirements

Mfg. Date: Mar.15, 2015

Exp. Date: Mar. 14, 2018

Tests	Specifications		Results
Characteristics	Appearance	white or almost white powder	Conform
	Solubility	Freely soluble in water, insoluble in ethanol(96%)	
Identification	A. IR spectrophotometry		Complies
	B. Reaction (a) of sulphates		
Appearance of solution	Clear and colorless		Complies
PH	3.8~5.6		4.3
Specific optical rotation	+10.0°~+14.0°		12.3°
Related substance	Impurity A	≤1.0%	0.07%
	Impurity E	≤1.0%	0.51%
	Impurity D	≤4.0%	0.30%
	Any other impurity	≤1.0%	0.08%
	Total impurity	≤6.0%	0.99%
Water	12.0~16.5%		14.8%
Sulphated ash	≤1.0%		0.06%
Assay (anhydrous substance)	(4R)-dihydrospectinomycin sulphate	≤2.0%	1.4%
	spectinomycin sulphate and (4R)-dihydrospectinomycin sulphate	93.0%~102.0%	97.8%
Heavy metals	≤20ppm		<20ppm
sulphate	21.0%~26.0%		22.8%
Microbial limit	Total bacteria count	≤500 cfu/g	<1cfu/g
	Total mold and microzyme	≤50 cfu/g	<1cfu/g
	Escherichia coli	absence	undetectable

结论: 本品按欧洲药典 8 和企业内控标准检验, 结果符合标准

**Conclusion:** conforms to EP8 and in-house requirements.

Reported by: Cai lanlan

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