

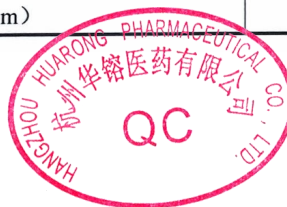
## CERTIFICATE OF ANALYSIS

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产品名称: 硫酸阿米卡星 (1: 2) Product Name: Amikacin Sulfate (1: 2)	总重量: 600.00KG Total Weight:	产品批号: RA2534A Batch No.:
报告日期: 2023.08.14 Reporting Date:	生产日期: 2022.09.18 Manufacturing Date:	有效期至: 2026.09.17 Expiry Date:

## Analytical Results

ITEMS (项目)	SPECIFICATIONS (标准)	RESULTS (结果)
Characters (性状)	White crystalline powder (白色结晶性粉末)	White crystalline powder (白色结晶性粉末)
Identification (鉴别)	It gives reaction of sulfates A. (硫酸盐鉴别反应: 应呈正反应)	Positive (呈正反应)
	Retention time: Accordance with RS B. HPLC: (样品应与对照品主峰保留时间一致)	Complies (符合规定)
	The spectrum of the sample corresponds to that of RS C. (样品的红外光谱应与对照品红外光谱一致)	Complies (符合规定)
Specific optical rotation (比旋度)	+76°~+84°	+80°
Crystallinity (结晶性)	Crystalline powder (结晶性粉末)	Complies (符合规定)
PH (酸度)	2.0~4.0	3.5
Loss on drying (干燥失重)	≤13.0%	10.2%
Residue on ignition (炽灼残渣)	≤1.0%	0.03%
Assay (Calculated on dried basis) (HPLC) (含量) (以干品计)	674μg/mg ~ 786μg/mg	736μg/mg
Residual solvents(GC) (溶剂残留)	Methanol≤3000ppm (甲醇≤3000ppm)	<7.2ppm
	Ethanol≤5000ppm (乙醇≤5000ppm)	625ppm



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Residual solvents(GC) (溶剂残留)	Acetone $\leq$ 2000ppm (丙酮 $\leq$ 2000ppm)	3ppm
	Acetonitrile $\leq$ 410ppm (乙腈 $\leq$ 410ppm)	< 1.9ppm
Bacterial endotoxins (Gel-clot) (细菌内毒素)	< 0.20EU/mg	< 0.20EU/mg
Microbial limits (微生物限度)	Total aerobic microbial count (TAMC) $\leq$ 100cfu/g (总需氧菌计数 $\leq$ 100cfu/g)	< 10cfu/g
	Total combined yeasts and molds count (TYMC) $\leq$ 10cfu/g (总霉菌和酵母菌计数 $\leq$ 10cfu/g)	< 10cfu/g
Solubility (溶解性)	Freely soluble in water, practically insoluble in acetone and in ethanol (易溶于水, 几乎不溶于丙酮和乙醇)	Complies (符合规定)
Conclusion: (结论)	The product conform to the USP 2021 and Client's requirement (本品符合美国药典 USP 2021 版及客户要求)	

