



ZHEJIANG JINHUA CONBA BIO-PHARM. CO., LTD.

浙江金华康恩贝生物制药有限公司

288 Jinqiu Road, Jinhua, Zhejiang 321016, China.  
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## Certificate of Analysis

Report No./报告书编号: 24081019-276364750

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Product Name/品名: Amikacin Sulfate / 硫酸阿米卡星 USP (1:2 SALT)

Produced In/产品来源: Jinxi Workshop No. 3 / 金西三车间

Report Date/报告日期: Dec. 15, 2024 Batch No./批号: H122412025

Packing/包装: 25KG/Drum

MFG. Date/生产日期: Dec. 25, 2024 Expiry Date/有效期至: Dec. 24, 2028

Batch Size/批量: 900KG

Tests/检测项目	Specifications/标准	Methods/方法	Results/结果
<b>Characters/性状</b>			
Appearance/外观	White crystalline powder 白色结晶性粉末	USP	Conforms/符合规定
Solubility/溶解度	Freely soluble in water/易溶于水	USP	Conforms/符合规定
<b>Identification /鉴别</b>			
A. IR/红外光谱	The IR absorption spectrum conforms to that of reference standard/供试品的红外吸收图谱应与硫酸阿米卡星USP对照品的吸收图谱一致	USP<197K>	Conforms/符合规定
B. HPLC/液相色谱	The retention time of the peak for Amikacin in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the assay./供试品溶液主峰的保留时间与对照品溶液主峰的保留时间一致。	USP<621>	Conforms/符合规定
C. Chemical Reaction/化学反应	It gives reaction of sulfates/应显硫酸盐的鉴别反应	USP<191>	Conforms/符合规定
<b>Tests/检查</b>			
Optical Rotation/比旋度	+76° ~+84°	USP<781S>	+80°
Crystallinity/结晶性	It Shows birefringence and extinction positions/呈双折射和消光位现象	USP<695>	Conforms/符合规定
pH	2.0~4.0	USP<791>	3.4
Loss on Drying/干燥失重	≤13.0%	USP<731>	9.4%
Residue on Ignition/炽灼残渣	≤1.0%	USP<281>	0.02%
<b>Residual Solvents/残留溶剂</b>			
Methanol/甲醇	≤0.3%	USP<467>	0.23%
Ethanol/乙醇	≤0.5%	USP<467>	Undetectable/未检出
Acetone/丙酮	≤0.5%	USP<467>	<0.01%
Acetonitrile/乙腈	≤0.041%	USP<467>	Undetectable/未检出
Bacterial Endotoxins /细菌内毒素	<0.33EU/mg	USP<85>	<0.33EU/mg

Manufacturing Site: 333 Wuxi Road, Tangxi Town, Jinhua, Zhejiang, China.  
生产地址: 中国浙江省金华市汤溪镇乌溪路333号



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Tests/检测项目	Specifications/标准	Methods/方法	Results/结果
Assay/含量			
Assay (dried substance)/含量 (干燥品计)	674~786µg/mg of $C_{22}H_{43}N_5O_{13}$	USP<621>	725µg/mg
Additional Tests/增加检测项目			
Microbial Limits/微生物限度			
TAMC/需氧菌总数	$\leq 10^3$ cfu/g	USP<61>	<10cfu/g
TYMC/霉菌和酵母菌总数	$\leq 10^2$ cfu/g	USP<61>	<1cfu/g
Escherichia Coli/大肠埃希菌	Absence/不得检出	USP<62>	Undetectable/未检出

Conclusion/结论: Conforming to current USP requirements/符合现行USP标准

Released by:  
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2024. 10. 16

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2024. 10. 15

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2024. 10. 15

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2024. 10. 15

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