



齐鲁天和惠世制药有限公司

QILU TIANHE PHARMACEUTICAL CO., LTD.

中国.山东.济南市历城区董家镇 849# 邮编: 250105

849 Dongjia Town, Licheng District, Jinan, Shandong, P.R.China 250105

产品检验证书

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)	代号: AA0214 Code No.:	产品批号: 121103426A Batch No.:
总重量: 192.77KGA Total Weight:	生产日期: 2012.11.30 Manufacturing Date:	有效期至: 2016.11.29 Expiry Date:
检验标准: Q-AA0214 Basis:	化验证书号: 121210209 COA No.:	报告日期: 2012.12.10 Reporting Date:

检验结果

Analytical Results

ITEMS (项目)	SPECIFICATIONS (标准)	RESULTS (结果)
Characters (性状)	White or off- white powder (白色或类白色粉末)	White powder (白色粉末)
Identification (鉴别)	A.IR: corresponds to that of the RS (样品的红外光谱应与对照品红外光谱一致。)	Meets the requirements (符合规定)
	B.TLC: corresponds to that of the RS (样品溶液应与对照品溶液主斑点一致)	Meets the requirements (符合规定)
	C.It gives reaction of sulphates (硫酸盐鉴别反应: 应呈正反应)	Positive (呈正反应)
pH	2.0—4.0	3.7
Optical rotation (比旋度)	+76°— +84°	+80°
Sulphate (硫酸盐)	23.3%—25.8%	24.4%
Loss on drying (干燥失重)	≤13.0%	10.9%
Assay(on dried basis) (含量) (以干品计)	96.5%—102.0%	99.2%
Bacterial endotoxin (细菌内毒素)	<0.20EU/mg	<0.20EU/mg
Microbiological examination (微生物)	The total aerobic microbial count ≤1000cfu/g (需氧菌数 ≤1000cfu/g)	<10cfu/g
	The total combined yeasts and molds count ≤100cfu/g (酵母菌和霉菌数 ≤100cfu/g)	<10cfu/g

QA manager

QA 负责人

QC manager

QC 负责人

Checker

复核人

Reporter

报告人

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Residual solvents (溶剂残留)	Methanol $\leq$ 3000ppm (甲醇 $\leq$ 3000ppm)	19ppm
	Ethanol $\leq$ 5000ppm 乙醇 $\leq$ 5000ppm	640ppm
	Acetonitrile $\leq$ 410ppm 乙腈 $\leq$ 410ppm	$<$ 1.9ppm
	Acetone $\leq$ 2000ppm 丙酮 $\leq$ 2000ppm	2ppm
Related substances (有关物质)	Impurity A $\leq$ 1.0% (杂质 A $\leq$ 1.0%)	$<$ 0.1%
	Impurity B $\leq$ 0.5% (杂质 B $\leq$ 0.5%)	$<$ 0.1%
	Impurity C $\leq$ 0.5% (杂质 C $\leq$ 0.5%)	$<$ 0.1%
	Impurity D $\leq$ 0.5% (杂质 D $\leq$ 0.5%)	$<$ 0.1%
	Amikacin B $\leq$ 0.5% (阿米卡星 B $\leq$ 0.5%)	0.4%
	Any other impurity $\leq$ 0.5% (其它任一杂质 $\leq$ 0.5%)	$<$ 0.1%
	Total impurities $\leq$ 1.5% (总杂质 $\leq$ 1.5%)	0.4%
Pyrogens (热原)	Meets the requirements (符合规定)	Meets the requirements (符合规定)
Conclusion (结论)	This product conforms to the specifications according to Ph. Eur. 7.5 requirements 本品按欧洲药典 7.5 版检验, 结果符合要求	

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