



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: 130401426A Batch No.:
总重量: 167.24KGA Total Weight:	生产日期: 2013.04.29 Manufacturing Date:	有效期至: 2017.04.28 Expiry Date:
检验标准: Q-AA0214A Basis:	化验证书号: 130513211 COA No.:	报告日期: 2013.05.13 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	3.8
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%	10.7%
Heavy metals (重金属)	≤20ppm	<20ppm
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

Reporter

报告人

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Residual solvents (溶剂残留)	Methanol $\leq$ 3000ppm (甲醇 $\leq$ 3000ppm)	36ppm
	Ethanol $\leq$ 5000ppm 乙醇 $\leq$ 5000ppm	777ppm
	Acetonitrile $\leq$ 410ppm 乙腈 $\leq$ 410ppm	$<$ 1.9ppm
	Acetone $\leq$ 2000ppm 丙酮 $\leq$ 2000ppm	3ppm
Related substances (有关物质)	Impurity A $\leq$ 0.5% (杂质 A $\leq$ 0.5%)	$<$ 0.1%
	Impurity B $\leq$ 0.5% (杂质 B $\leq$ 0.5%)	$<$ 0.1%
	Impurity F $\leq$ 0.5% (杂质 F $\leq$ 0.5%)	0.2%
	Impurity H $\leq$ 0.5% (杂质 H $\leq$ 0.5%)	0.4%
	Impurity I $\leq$ 0.5% (杂质 I $\leq$ 0.5%)	$<$ 0.1%
	Any other impurity $\leq$ 0.5% (其它任一杂质 $\leq$ 0.5%)	0.4%
	Total impurities $\leq$ 1.5% (总杂质 $\leq$ 1.5%)	1.2%
Pyrogens (热原)	Meets the requirements (符合规定)	Meets the requirements (符合规定)
Conclusion: This product conforms to the specifications according to Ph. Eur. 7.6 and in-house requirements (结论): 本品按欧洲药典 7.6 版质量标准检验, 结果符合要求		

QA manager

QA 负责人

QC manager

QC 负责人

Checker

复核人

Reporter

报告人

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