



齐鲁天和惠世制药有限公司

QILU TIANHE PHARMACEUTICAL CO., LTD.

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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: 140502826A Batch No.:
总重量: 152.64KGA Total Weight:	生产日期: 2014.05.06 Manufacturing Date:	复检期至: 2015.11.05 Retest Period:
检验标准: Q-AA0214C/ R0-CEP 2010-308-Rev 00 Basis:	化验证书号: 140521210 COA No.:	报告日期: 2014.05.21 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%	24.2%
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

2014.5.22

QC manager

QC 负责人

Checker

复核人

Reporter

报告人

2014.5.21



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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)	代号: AA0214	产品批号: 140502826A
Product Name: Amikacin Sulfate (1: 2)	Code No.:	Batch No.:
总重量: 152.64KGA	生产日期: 2014.05.06	复检期至: 2015.11.05
Total Weight:	Manufacturing Date:	Retest Period:
检验标准: Q-AA0214C/ R0-CEP 2010-308-Rev 00	化验证书号: 140521210	报告日期: 2014.05.21
Basis:	COA No.:	Reporting Date:

检验结果

Analytical Results

ITEMS (项目)	SPECIFICATIONS (标准)	RESULTS (结果)
Residual solvents (溶剂残留)	Methanol $\leq$ 3000ppm (甲醇 $\leq$ 3000ppm)	64ppm
	Ethanol $\leq$ 5000ppm (乙醇 $\leq$ 5000ppm)	538ppm
	Acetone $\leq$ 2000ppm (丙酮 $\leq$ 2000ppm)	3ppm
	Acetonitrile $\leq$ 410ppm (乙腈 $\leq$ 410ppm)	<1.9ppm
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%)	0.2%
	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%)	0.2%
	Total impurities $\leq$ 1.5% (总杂质 $\leq$ 1.5%)	0.8%
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. 8.0 and in-house requirements/ R0-CEP 2010-308-Rev.00

(结论): 本品按欧洲药典 8.0 版及内控/ R0-CEP 2010-308-Rev.00 标准检验, 结果符合要求

QA manager

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2014.5.22

QC manager

QC 负责人

2014.5.21

Checker

复核人

2014.5.21

Reporter

报告人

2014.5.21