



新昌县九信药业有限公司

Xinchang JiuXin Pharmaceutical Co.,Ltd

质量检测报告书

Certificate of analysis

报告单号 (COA no.) TS-QCSA00107003-Report02-00

检品名称 product	麻保沙星 marbofloxacin	批号 batch no.	141204-1
包装 packaging size	25kg /桶 (drum)	数量 quantity	100kg
生产日期 MFG DATE	04/12/2014(d/m/y)	报告日期 reporting date	08/12/2014(d/m/y)
执行标准 according to	欧洲药典(EP8)	复测日期 Retest date	03/12/2017(d/m/y)

Tests		Spec.	Results
Characters	appearance	Light yellow crystalline powder	Conforms
	solubility	Slightly soluble in water, sparingly soluble or slightly soluble in methylene chloride, very slightly soluble in ethanol(96%)	Conforms
Identification		IR: conforms to the reference spectra	Conforms
Absorbance		≤0.20	0.06
loss on drying		≤0.5%	0.03%
sulphated ash		≤0.1%	0.05%
heavy metals		≤20ppm	<20ppm
related substances(HPLC)	Impurity A	≤0.1%	not detected
	Impurity B	≤0.1%	not detected
	Impurity C	≤0.2%	0.13%
	Impurity D	≤0.2%	not detected
	Impurity E	≤0.2%	not detected
	any other single impurity	≤0.2%	not detected
	total impurities	≤0.5%	0.13%
residual solvents	ethanol ≤5000ppm		569.4ppm
	toluene≤890ppm		666.7ppm
	methylene chloride≤600ppm		3.3ppm
Assay (HPLC)	C ₁₇ H ₁₉ FN ₄ O ₄ :96.0~102.0% (Dried substance)		99.7%

结论: 本品按欧洲药典 8 版标准检验, 结果符合标准

Conclusion: conforms to EP8

Reported by: Cai lanlan

reviewed by: Pan fangfang

approved by: Cai lanlan