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

检字号（serial no.）038

检品名称 product	延胡索酸泰妙菌素 tiamulin fumarate	批号 batch no.	B21140212
包装 packaging size	1kg/袋（sack）	数量 quantity	1kg
生产日期 MFG DATE	17/02/2014(d/m/y)	报告日期 reporting date	19/02/2014(d/m/y)
执行标准 according to	美国药典（USP）	失效日期 Expiry date	16/02/2016(d/m/y)

Tests	acceptance criteria		results
description	White or almost white crystal powder, odorless and tasteless		Conforms
melting point	143~152℃		147℃
specific rotation	+24° ~ +28°		+24°
fumarate	83.7~87.3mg		86.5mg
identification	1. IR: conforms to the reference standard 2. HPLC: the retention time of the test solution corresponds to that of the standard solution.		Conforms
PH	3.4~4.1		3.5
chromatographic purity	any identified impurity	≤1.0%	Conforms
	any unidentified impurity	≤0.5%	
	Total impurities	≤3.0%	
color and clarity of solution	≤0.030(650nm)		0.05
	≤0.150(400nm)		0.014
Residual solvents	应符合规定 conforms		conforms
loss on drying	≤0.1%		0.1 %
residue on ignition	≤0.1%		0.08%
heavy metals	≤0.001%		< 0.001%
Assay on dried	97.0~102%		98.6%

结论：本品按美国药典标准检验，结果符合规定

Conclusion: conforms to USP specification for tiamulin fumarate

Reported by: Cai lanlan　　reviewed by: Pan fangfang　　approved by: Cai lanlan

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