



新昌县九信药业有限公司

JIU XIN 九信药业  
Pharmaceutical Industry

Xinchang JiuXin Pharmaceutical Co.,Ltd

## 质量检测报告书

### Certificate of analysis

检字号 (serial no.) D1291408020

检品名称 product	阿奇霉素 azithromycin	批号 batch no.	129-140808-1
包装 packaging size	25kg/桶 (drum)	数量 quantity	200kg
生产日期 MFG DATE	06/08/2014(d/m/y)	报告日期 reporting date	10/08/2014(d/m/y)
执行标准 according to	美国药典 (USP) 26	失效日期 Expiry date	05/08/2017(d/m/y)

Tests		acceptance criteria	results	
description	appearance	White or almost white crystalline powder	White crystalline powder	
	solubility	Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride.	Conforms	
identification		1. IR: conforms to the azithromycin RS spectrum 2. HPLC: the retention time of azithromycin peak in the chromatogram of the assay preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.	Conforms	
specific rotation		-45° ~ -49° (anhydrous substance 20mg/ml dehydrated alcohol)	-48°	
crystallinity		meets the requirements	Conforms	
PH		9.0~11.0(0.1g/50ml methanol-water (1:1))	9.9	
water		4.0%~5.0%	4.5%	
residue on ignition		≤0.3%	0.04%	
heavy metals		≤0.0025%	< 0.0025%	
Residual solvents		(1)Methylene chloride	≤600ppm	not detected
		(2) Acetone	≤5000ppm	506ppm
assay (HPLC)		C <sub>38</sub> H <sub>72</sub> N <sub>2</sub> O <sub>12</sub> :945~1030ug/mg(anhydrous substance)	969ug/mg	

结论: 本品按美国药典 26 版标准检验, 结果符合规定

**Conclusion:** conforms to USP26 specification for azithromycin

备注 (note): 松密度 (bulk density) 0.51g/ml \*为内控项目 (In-house specifications)

Reported by: Cai lanlan

reviewed by: Pan fangfang

approved by: Cai lanlan