



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.) C1081408008

检品名称 product	罗红霉素 Roxithromycin	批号 batch no.	140807-1
包装 packaging size	25 /桶 (drum)	数量 quantity	300kg
生产日期 MFG DATE	29/07/2014(d/m/y)	报告日期 reporting date	02/08/2014(d/m/y)
执行标准 according to	欧洲药典 8.0 版 EP8.0	复测日期 Retest date	28/07/2017(d/m/y)

Tests		Spec.	Results
Characters	appearance	white or almost white crystalline powder	A white crystalline powder
	solubility	Very slightly soluble in water, freely soluble in acetone, in alcohol and in methylene chloride. It is slightly soluble in dilute hydrochloric acid.	Conforms
identification	IR: conforms to the reference spectra		Conforms
	HPLC: Similar in retention time and size to the principal peak of the reference solution(a)		
Appearance of solution	clear and colorless (0.2g/20ml methanol)		Conforms
specific optical rotation	-93° ~ -96° (anhydrous substance 0.500g/50ml acetone)		-95°
related substances	Impurity G	≤ 1.0%	0.09%
	Impurity A, B, C, D, E, F, H, I, J	≤ 0.5%	0.31%
	total impurities	≤ 3.0%	1.7%
heavy metals	≤10ppm		<10ppm
water	≤3.0%		2.2%
sulphated ash	≤0.1%		0.02%
residual solvents	methanol	≤3000ppm	286ppm
	acetone	≤5000ppm	not detected
	methylene chloride	≤600ppm	not detected
Assay	C ₄₁ H ₇₆ N ₂ O ₁₅ :96.0~102.0% (anhydrous substance)		99.0%

结论: 本品按欧洲药典 8.0 版标准检验, 结果符合标准

Conclusion: conforms to EP8.0

备注 (note): 松密度 (bulk density) 0.56/ml

Reported by: Cai lanlan

reviewed by: Pan fangfang

approved by: Cai lanlan