Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

报告单编号（COA NO.）TS-QCSA00109007-Report01-00　　检字号(Serial No.)**D1031503001**

检品名称 Product	阿奇霉素 Azithromycin	批　号 Batch No.	103-150219-1
包　装 Packaging Size	5Kg/桶（drum）	数　量 Quantity	5kg
生产日期 MFG Date	14/02/2015 (d/m/y)	报告日期 Reporting Date	06/03/2015(d/m/y)
执行标准 According to	美国药典（USP37）	复测日期 Retest Date	13/02/2018 (d/m/y)

检验项目（Tests）		标 准 规 定 (Acceptance Criteria)		结 果 (Results)
*性 状 Characters	Appearance	白色或类白色粉末 White or almost white powder.		白色粉末 White powder
	Solubility	几乎不溶于水，易溶于无水乙醇和二氯甲烷 Practically insoluble in water, freely soluble in anhydrous ethanol and in methylene chloride.		符 合 Conforms
鉴　别 Identification		(1) IR：红外光吸收图谱应与对照品的图谱一致 IR: Conforms to the spectrum of Azithromycin RS. (2) HPLC：供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 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.		符 合 Conforms
比旋度 Specific rotation		-45° ～ -49°		-47°
结晶性 Crystallinity		应符合规定 Meets the requirements		符 合 Conforms
碱　度 pH		9.0～11.0 (2mg /ml methanol-water (1:1))		10.0
水　分 Water		4.0%～5.0%		4.5%
炽灼残渣 Residue on ignition		≤0.3%		<0.01%
重金属 Heavy metals		≤25ppm		<25ppm
有关物质 Related substances (HPLC Test 2)		Azaerythyomycin A (ImpurityA)	≤0. 5%	<0. 10%
		Azithromycin B (ImpurityB)	≤1. 0%	0. 60%
		Azithromycin C (ImpurityC)	≤0. 5%	0. 14%
		Desosaminylazithromycin (Impurity J)	≤0. 3%	0. 20%
		3′-(N,N-didemethyl) azithromycin (Impurity E)	≤0. 5%	Not detected
		Azithromycin related compound F (Impurity F)	≤0. 5%	<0. 10%
		3′-N-demethyl-3′-N-[(4-methylphenyl)sulfonyl] azithromycin (ImpurityG)	≤0. 5%	Not detected
		N-demethylazithromycin (ImpurityI)	≤0. 7%	Not detected
		Azithromycin N-oxide (Impurity L)	≤0. 5%	Not detected

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	3′-(N,N-didemethyl)-3′-N-formylazithromycin (Impurity M)	≤0.5%	<0.10%
	3′-De(dimethylamino)-3′-oxoazithromycin (ImpurityN)	≤0.5%	Not detected
	2-Desethyl-2-propylazithromycin (ImpurityO)	≤0.5%	0.12%
	Azithromycin impurity P (ImpurityP)	≤0.2%	<0.10%
	Any other impurity	≤0.2%	<0.10%
	Total impurities	≤3.0%	1.1%
含 量（HPLC）Assay	以无水物计算，含 $C_{38}H_{72}N_2O_{12}$ 应为 945～1030 μg/mg 945～1030 μg/mg (Anhydrous substance)		980 μg/mg
残留溶剂 Residual solvents	（1）二氯甲烷 Methylene Chloride	≤600ppm	Not detected
	（2）丙 酮 Acetone	≤5000ppm	378ppm

结论：本品按美国药典 37 版标准检验，结果符合规定

Conclusion: conforms to USP37specification for Azithromycin

备注(note)：　松密度（bulk density：0.50g/ml）

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