

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS(OUTLAND)

编号/SN: ZLJ565-00

药品名称 Drug Name	利福平 Rifampicin	数量 Quantity	25Kg
批号 Batch No.	S1201401003	生产日期 Date of manufacture	2013.12.28
检验依据 Analysis base on	USP34	报告日期 Date of report	2014.01.06
包装规格 Packing Standard	25Kgs / 桶 25Kgs / drum	失效日期 Date of Expiry	2016.12.28
样品来源 Source of Sample	沈阳原料药 Raw material form Shenyang Antibiotic Manufacturer	备注 Remark	-----
检验项目 Test Item	标准规定 Specifications		检验结果 Results
鉴别 Identification	应呈正反应 Positive		呈正反应 Positive
性状 Characteristics	棕红色结晶性粉末 Brownish Red brown- crystalline powder		符合规定 Qualified
酸度 pH Acidity pH	4.5—6.5		6.0
相关物质 Related Substances	Rifampicin quinone (醌式利福平) $\leq 1.5\%$		0.18%
	One peak (单峰) $\leq 1.0\%$		0.68%
	Sum of peaks (杂峰总和) $\leq 3.5\%$		2.28%
干燥失重 Loss on Drying	$\leq 1.0\%$		0.3%
密度 Density	$\geq 0.7\text{g/cm}^3$		0.75g/cm ³
结晶性 Crystallinity	Should comply the test		符合规定 Qualified
溶解性 Solubility	易溶于氯仿, 溶于乙酸乙酯和甲醇, 微溶于水 Freelysoluble in chloroform, soluble in ethyl acetateand methanol, very slightly soluble in water.		符合规定 Qualified
细菌 Total quantity of bacterium	$\leq 1000\text{cfu/g}$		符合规定 Qualified
霉菌和酵母菌 Total quantity of Mould and yeast	$\leq 100\text{cfu/g}$		符合规定 Qualified
大肠埃希菌 Escherichia coli/g	Not found in each 1g		符合规定 Qualified
含量 (以干燥品计) Assay (Calculated on the Dried basis)	95.0—103.0 %		98.0%
结论: 本品符合英国药典 34 版规定 Conclusion: The product above-mentioned is in conformity with USP 34			
备注: Remarks:			
负责人 Director	吴月	复核员 Checker	李琪
			检验员 Tester

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