

Items 项目	Specification 标准	Result 结果
Characters 性状		
Appearance 外观	White or almost white powder 白色或类白色粉末	White powder 白色粉末
Solubility 溶解度	Very soluble in Methanol, acetone, acetic ether and dissolved in ethanol.在甲醇、丙酮、乙酸乙酯中易溶, 在乙醇中溶解	Conforms 符合规定
Specific rotation 比旋度	-22° ~ -26°	-24°
Identification 鉴别		
Identification A(by IR) 鉴别 A	The IR spectrum of the substance to be examined corresponds to the spectrum of Tulathromycin RS.本品的红外吸收图谱应与对照品的图谱一致	Conforms 符合规定
Identification B(by HPLC) 鉴别 B	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.在含量测定项下记录的色谱图中, 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	Conforms 符合规定
Related substances 有关物质		
阿奇霉素 A Azathramycin	Not more than 2.0% 不得过 2.0%	0.041%
4'-环氧-阿奇霉素 A 4'-epoxy-Azathramycin	Not more than 2.0% 不得过 2.0%	Not detected 未检出
4-OCBZ-4'-环氧-阿奇霉素 A 4-OCBZ-4'-epoxy-Azathramycin	Not more than 1.5% 不得过 1.5%	Not detected 未检出
Other Single Impurities 其他单一杂质	Not more than 0.5% 不得过 0.5%	0.1%
Total Impurities 总杂	Not more than 3.0% 不得过 3.0%	0.46%
Loss on drying 干燥失重	Not more than 2.5% 不得过 2.5%	1.7%
Sulfated ash 炽灼残渣	Not more than 0.1% 不得过 0.1%	0.04%
Heavy metals 重金属	Not more than 20ppm 不得过 20ppm	Conforms 符合规定
Residual solvents 残留溶剂		
Methanol 甲醇	Not more than 3000ppm 不得过 3000ppm	44 ppm
Acetone 丙酮	Not more than 5000ppm 不得过 5000ppm	19 ppm
Isopropyl ether 异丙醚	Not more than 5000ppm 不得过 5000ppm	Not detected 未检出
Microbial limit 微生物限度		
Total aerobic microbial 需氧菌数	Not more than 10 ² cfu/g 不得过 10 ² cfu/g	<10cfu/g
Total Combined Yeasts and Molds 霉菌和酵母菌数	Not more than 10 ¹ cfu/g 不得过 10 ¹ cfu/g	<10cfu/g
Escherichia 大肠埃希菌	Absent/g 不得检出/g	Absent 未检出
Bacterial endotoxins 细菌内毒素	Less than 2EU/mg 小于 2EU/mg	Conforms 符合规定
Assay 含量	The Sum of TulathromycinA and TulathromycinB should be 96.0%~102.0% (on the dried basis).按干燥品计, 含泰拉霉素 A 和泰拉霉素 B 之和应为 96.0%~102.0%。	97.6%
Conclusion: The product complies with the enterprise standard.结论: 本品符合企业内控标准.		