



检验报告单  
Certificate of Analysis

产品名称:	硫酸多黏菌素 B		
Product Name:	Polymixin B Sulphate		
CAS NO:	1405-20-5		
批号 Batch NO.	ZET190504	生产日期 Manufacture Date	2019.05.04
数量 quantity	10kg	检验日期 Analysis Date	2019.05.04

项目 Test	标准参数 Specification	测试结果 Result
外观 Appearance	白色或类白色, 有吸湿性粉末 White or off-white, hygroscopic powder	白色, 易吸湿性粉末 White, hygroscopic powder
鉴别 Identification	(1) 硫酸盐显色反应 Sulfate chromogenic reaction	符合 Conform
	(2) 应与对照品主峰保留时间一致 Should be consistent with the main peak retention time of the control compound	符合 Conform
pH	5.0-7.5(5mg/ml)	6.0
溶解性 Solubility	易溶于水, 微溶于乙醇 Soluble in water, slightly soluble in ethanol	符合 Conform
比旋度 Specific rotation	-78°~-90°	-83°
干燥失重 Loss on drying	≤7%	4.0%
苯丙氨酸含量 (干品计) Phenylalanine (on dried basis)	9%~12%	10.0%
硫酸盐 Sulfate	15.5%~17.5%	16.9%
有关物质 Related substance	任一单杂 ≤3.0% Single impurity ≤3.0%	2.14%
	总杂 ≤17.0% Total impurities ≤17.0%	8.6%
纯度和 (干品计) Purity (on dried basis)	≥80.0%	93.5%



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B <sub>3</sub> %	≤6.0%	1.29%
B <sub>H</sub> %	≤15.0%	7.67%
炽热残渣 Residue on Ignition	≤0.75%	0.52%
生物效价(干品计) Biological value (on dried basis)	≥6000U/mg	8016U/mg
结论 Conclusion	符合 USP40 Conforms USP40	



Inspector/date:王丽 Reporter/date:李华 QC manager/date:陈亮亮