



# 台州友盛化工有限公司

TAIZHOU YOUSHENG CHEMICAL CO., LTD

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## CERTIFICATE OF ANALYSIS

名称 Product name	硫酸多粘菌素 B Polymyxin B Sulfate	批号 Batch No.	20200504
CAS No.	1405-20-5	生产日期 Manufacturing date	May.10,2020
规格 Package size	1.0Kg/铝听 1.0Kg/Aluminum can	复验日期 Retest date	May.09,2022
数量 Quantity	13.881Kg	报告日期 Report date	May.12,2020
检验项目 Items	质量指标 Specification	检验结果 Results	
外观 Appearance	本品为白色或类白色粉末，具有引湿性。 White or almost white powder,hygroscopic.	符合要求 Conforms	
溶解性 Solubility	本样品在水中易溶，在乙醇中微溶。 Soluble inwater, slightly soluble in alcohol.	符合要求 Conforms	
鉴别 Identification	A.样品溶液中主要峰的保留时间与标准溶液的保留时间一致。 The retention times of the major peaks from the sample solution correspond to those of the standard solution,as obtained in the test for composition of Polymyxins. B.取本品约 2MG，加水 5ML，溶解后，加 2.5N 氢氧化钠溶液 5ML,振摇，加 5 滴 10mg/ml 硫酸铜振摇，应渐显红紫色。 To the sample solution add 5ml of 2.5N sodium hydroxide,and mix,Add 5 drops of 10mg/ml of cupric sulfate shaking after the	符合要求 Conforms	

	addition of each drop,A reddish-violet color is produced. C.本品的水溶液显硫酸盐的鉴别反应。 It gives reaction of sulphate.		
PH	5.0~7.5		5.7
干燥失重 Loss on drying	NMT7.0%		4.4%
灼烧残渣 Residue on ignition	NMT5.0%		0.3%
含量 Assay (On the dried basis)	不得低于 6000IU/mg Not less than 6000IU/mg		8150IU/mg
有关物质 Related substances	最大单杂 Any impurity	NMT 3.0%	1.7%
	总杂 Total impurity	NMT17.0%	4.8%
多粘组分分析 Composition of Polymyxins	B3	NMT6.0%	1.0%
	B1-II	NMT15.0%	12.0%
	总和 Sum of B1,B2, B3and B1-I	NLT80.0%	94.6%
结论 Conclusion	结果符合 USP42 标准。The results conform to the standard of USP42		

检验者: \_\_\_\_\_

复核者: \_\_\_\_\_

QC 负责人: \_\_\_\_\_

QA 负责人: \_\_\_\_\_