

SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Polymyxin B Sulphate (Cas 1405-20-5)		
Batch No.	HON2112204U	Mfg. date	2021.12.22
Rep. Date	2022.01.12	Retest Date	2023.12.21
Packaging	1kg/Carton	Batch Quantity	12.25kg
Test Items	Standards: USP43		Results
Characters	White to slightly yellow powder		Almost white powder
Identification	Should conform		Conforms
PH	5.0~7.5		6.4
Loss on drying	NMT7.0%		0.1%
Residue on ignition	NMT5.0%		1.1%
Heavy metals	NMT20ppm		<20ppm
Sum of PB1, B2, B3, B1-I	NLT80.0%		92.4%
PB3	NMT6.0%		1.2%
PB1-I	NMT15.0%		10.5%
Total Impurities	NMT17.0%		6.0%
Single impurity	NMT3.0%		1.5%
Microbial requirements	TAMC: NMT10cfu/g TYMC: NMT10cfu/g		<1cfu/g <1cfu/g
Assay (on dried basis)	NLT6000IU/MG		6667IU/MG
Conclusion	It meets the requirements of USP43 Standards		
Storage	Store in a well-closed container at ambient temperature(2~8°C)		
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