



CERTIFICATE OF ANALYSIS

Product : **POLYMXIN B SULFATE**
Product number : P0145
Batch number : 018972
Date of production : xx-07-2021
Date of analysis : 07-07-2021
Date of expiry : 31-07-2026

Packaging and storage : store in a well-closed container at 2 – 8 °C

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white or almost white powder	complies		hygroscopic
Identification	conform	complies		
pH	5.0 – 7.0	6.5		2.0 % in H ₂ O
Related substances:				HPLC
- each impurity	≤ 3.0	1.3	%	
- total of impurities	≤ 17.0	2.9	%	
Sulphate	15.5 – 17.5	16.3	%	dried substance
Loss on drying	≤ 6.0	1.0	%	
Sulphated ash	≤ 0.75	0.62	%	
Microbiological Assay	≥ 6500	8693	IU/mg	dried substance
		8606	IU/mg	
Assay:				dried substance, HPLC
- sum polymixin B1, B2, B3+B1-I	≥ 80.0	97.1	%	
- polymixin B3	≤ 6.0	2.1	%	
- polymixin B1-I	≤ 15.0	7.9	%	

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

J. van der Eem, MSc, pharmacist
Department of Quality Control Duchefa BV

Date: 24-12-2024

The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.

