

CERTIFICATE OF ANALYSIS

Product : **POLYMXIN B SULFATE**
Non-sterile, micronized
Product number : P0145
Batch number : 013748
Date of production : xx-01-2018
Date of analysis : 23-02-2018
Date of expiry : 31-01-2023

Packaging and storage : store protected from light at 2 – 8 °C in airtight containers.

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white or almost white powder	complies		hygroscopic
Identification	conform	complies		
pH	5.0 – 7.0	6.4		2.0% in H ₂ O
Specific optical rotation	-78 – -90	-87	°	
Related substances:				HPLC
- major impurity	≤ 3.0	2.2	%	
- sum of impurities	≤ 17.0	14.2	%	
Sulphate	15.5 – 17.5	17.2	%	dried substance
Loss on drying	≤ 6.0	1.1	%	3h, 60°C, P ₂ O ₅ , < 670 Pa
TAMC	≤ 10	< 10	cfu/g	
TYMC	≤ 10	< 10	cfu/g	
Assay (microbiological):	≥ 6500	7947	IU/mg	dried substance
	≥ 650	795	µg/mg	
Assay (HPLC):				dried substance
- sum of polymixin B1, B2, B3 and B1-I	≥ 80.0	91.5	%	
- polymixin B3	≤ 6	3.8	%	
- polymixin B1-I	≤ 15	9.2	%	

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

Conclusion: approved

Released by:

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drs. M. van Wissen, pharmacist
Department of Quality Control Duchefa B.V.

Date: 03-05-2018

*Schellekens
S. de Bree*

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