

CERTIFICATE OF ANALYSIS

Product : **POLYMYXIN B SULPHATE**
 Product number : P0145
 Batch number : 015758
 Date of production : xx-04-2020
 Date of analysis : 26-06-2020
 Date of expiry : 31-03-2025

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	6.0		2.0 % in H ₂ O
Related substances:				HPLC
- each impurity	≤ 3.0	2.2	%	
- total of impurities	≤ 17.0	14.7	%	
Sulphate	15.5 – 17.5	17.4	%	dried substance
Loss on drying	≤ 6.0	1.4	%	
Assay (Microbiological):	≥ 6500	8002	IU/mg	dried substance
		800	µg/mg	
Assay (HPLC):				dried substance
- sum polymyxins B1, B2, B3 and B1-I	≥ 80.0	85.3	%	
- polymyxin B3	≤ 6.0	4.0	%	
- polymyxin B1-I	≤ 15.0	7.8	%	

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

Conclusion: approved

Released by:

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

Date: 14-10-2020



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

Duchefa Biochemie B.V.