

CERTIFICATE OF ANALYSIS

Product : **POLYMYXIN B SULPHATE**
 Product number : P0145
 Batch number : 014760
 Date of production : xx-03-2019
 Date of analysis : 06-06-2019
 Date of expiry : 28-02-2024

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	6.3		2.0 % in H ₂ O
Related substances:				HPLC
- each impurity	≤ 3.0	2.2	%	
- total of impurities	≤ 17.0	13.8	%	
Sulphate	15.5 – 17.5	16.6	%	dried substance
Loss on drying	≤ 6.0	0.8	%	
Assay (Microbiological):	≥ 6500	8092	IU/mg	dried substance
		784	µg/mg	
Assay (HPLC):				dried substance
- sum polymyxins B1, B2, B3 and B1-I	≥ 80.0	86.2	%	
- polymyxin B3	≤ 6.0	4.4	%	
- polymyxin B1-I	≤ 15.0	8.5	%	

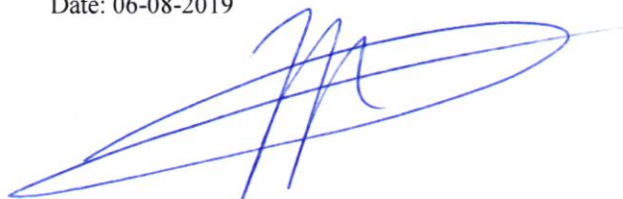
This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

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

Date: 06-08-2019



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

Duchefa Biochemie B.V.