

CERTIFICATE OF ANALYSIS

Product : **POLYMXIN B SULFATE**
 Product number : P0145
 Batch number : 010939
 Date of production : xx-10-2014
 Date of analysis : 03-12-2014
 Date of expiry : 30-09-2019

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
Specific optical rotation	-78 – -90	-88	°	dried substance
Related substances:				HPLC
- each impurity	≤ 3.0	2.1	%	
- total of impurities	≤ 17.0	14.3	%	
Phenylalanine	9 – 12	11	%	
Sulphate	15.5 – 17.0	16.5	%	dried substance
Loss on drying	≤ 6.0	1.6	%	
Sulphated ash	≤ 0.75	0.08	%	
Heavy metals	≤ 20	complies	ppm	
Microbiological Assay	≥ 6500	7825	IU/mg	dried substance
		783	µg/mg	
Assay:				dried substance, HPLC
- sum polymixin B1, B2,B3+ B1-I	≥ 80.0	84.3	%	
- polymixin B3	≤ 6.0	3.4	%	
- polymixin B1-I	≤ 15.0	7.7	%	

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 B.V.

Date: 05-01-2015



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