

CERTIFICATE OF ANALYSIS

Product : **POLYMIXIN B SULFATE**
Non-sterile, micronized

Product number : P0145

Batch number : 013231

Date of production : xx-09-2016

Date of analysis : 25-04-2017

Date of expiry : 31-08-2021

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	6.5		2.0% in H ₂ O
Specific optical rotation	-78 – -90	-87	°	2.0% in H ₂ O, dried substance HPLC
Related substances:				
- major impurity	≤ 3.0	2.1	%	
- sum of impurities	≤ 17.0	15.0	%	
Sulphate	15.5 – 17.5	16.6	%	dried substance
Loss on drying	≤ 6.0	1.4	%	3h, 60°C, P ₂ O ₅ , < 670 Pa
Heavy metals	≤ 20	complies	ppm	
Assay (microbiological):	≥ 6500	7931	IU/mg	dried substance
	≥ 6500	793	µg/mg	
Assay (HPLC):				dried substance
- sum of polymixin B1, B2, B3 and B1-I	≥ 80.0	89.6	%	
- polymixin B3	≤ 6.0	3.4	%	
- polymixin B1-I	≤ 15.0	8.9	%	

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: 22-01-2018



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