CERTIFICATE OF ANALYSIS

Product	:	**POLYMIXIN B SULFATE**
Product number	:	P0145
Batch number	:	012563
Date of production	:	xx-05-2015
Date of analysis	:	07-08-2015
Date of expiry	:	30-04-2020
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	6.2		2.0% in H_2O
Specific optical rotation	-78 – -90	-87	°	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	16.7	%	dried substance
Loss on drying	≤ 6.0	1.0	%	
Sulphated ash	≤ 0.75	0.07	%	
Heavy metals	≤ 20	< 20	ppm	
Microbiological Assay	≥ 6500	7943	IU/mg	dried substance
		794	µg/mg	
Assay:				dried substance, HPLC
- sum polymixin B1, B2,B3+ B1-I	≥ 80.0	90.0	%	
- polymixin B3	≤ 6.0	3.5	%	
- polymixin B1-I	≤ 15.0	8.7	%	

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 BV

Date: 01-12-2016

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