CERTIFICATE OF ANALYSIS

Product	:	**NEOMYCIN SULPHATE**
Product number	:	M0135
Batch number	:	013987
Quality	:	Ph. Eur. 9.1
Date of analysis	:	23-06-2017
Expiry date	:	30-09-2020
Packaging and storage	:	store at room temperature in a well-closed container

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	white or yellowish-white powder	complies		hygroscopic
Solubility	soluble in water			20°C / 300 g/l
Identification:				
- A (HPLC)	conform	complies		
- B (sulphate)	conform	complies		
pH	5.0 – 7.5	6.6		1% in H_2O
Specific optical rotation	+53.5 – +59.0	+57.5	°	10% in H_2O, dried substance
Related substances:				HPLC
- Neamine	≤ 2.0	< 2.0	%	
- Neomycin C	3.0 – 15.0	12.1	%	
- any other impurity	≤ 5.0	< 5.0	%	
- total of other impurities	≤ 15.0	< 15.0	%	
Sulphate	27.0 – 31.0	27.8	%	dried substance
Loss on drying	≤ 8.0	2.1	%	3 h, 60°C, P_2O_5 < 0.7 kPa,
Sulphated ash	≤ 1.0	0.31	%	
Assay	≥ 680	690	IU/mg	dried substance

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: 24-08-2018

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

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