

## **CERTIFICATE OF ANALYSIS**

Product : NEOMYCIN SULPHATE

Product number : M0135
Batch number : 017530
Date of analysis : 12-05-2020
Expiry date : 31-03-2024

Packaging and storage : store at room temperature in a well-closed container

Appearance Solubility Identification:	<b>SPECIFICATION</b> white or yellowish-white powder soluble in water	RESULT complies	UNITS	REMARKS hygroscopic 20°C / 300 g/l
- A (HPLC)	conform	complies		
- B (sulphate)	conform	complies		
pH	5.0 - 7.5	6.2		1% in H <sub>2</sub> O
Specific optical rotation	+53.5 - +59.0	+57.1	o	10% in H <sub>2</sub> O, dried
				substance
Related substances:				HPLC
- Neamine	≤ 2.0	< 1.0	%	
- Neomycin C	3.0 - 15.0	10.0	%	
- any other impurity	≤ 5.0	< 2.4	%	
- total of other impurities	≤ 15.0	3.8	%	
Sulphate	27.0 - 31.0	27.8	%	dried substance
Loss on drying	≤ 8.0	6.5	%	3 h, $60^{\circ}$ C, $P_2O_5$ <
				0.7 kPa,
Sulphated ash	≤ 1.0	0.4	%	
Assay	≥ 680	724	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: 31-01-2023

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