

CERTIFICATE OF ANALYSIS

Product : **NEOMYCIN SULPHATE**
 Product number : M0135
 Batch number : 018150
 Date of analysis : 30-08-2023
 Expiry date : 30-09-2025

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	6.0		1% in H ₂ O
Specific optical rotation	+53.5 – +59.0	+55.8	°	10% in H ₂ O, dried substance HPLC
Related substances:				
- Neamine	≤ 2.0	< 1.0	%	
- Neomycin C	3.0 – 15.0	11.1	%	
- any other impurity	≤ 5.0	< 2.4	%	
- total of other impurities	≤ 15.0	5.5	%	
Sulphate	27.0 – 31.0	27.4	%	dried substance
Loss on drying	≤ 8.0	6.1	%	3 h, 60°C, P ₂ O ₅ < 0.7 kPa,
Sulphated ash	≤ 1.0	0.2	%	
Assay	≥ 680	711	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: 27-11-2023



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