

CERTIFICATE OF ANALYSIS

Product : NEOMYCIN SULPHATE
Product number : M0135
Batch number : 012776
Quality : Ph. Eur. 8.8
Date of analysis : 13-01-2017
Expiry date : 30-08-2020

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	6.5		1% in H ₂ O
Specific optical rotation	+53.5 – +59.0	+ 55.7	°	10% in H ₂ O, dried substance HPLC
Related substances:				
- Neamine	≤ 2.0	< 2.0	%	
- Neomycin C	3.0 – 15.0	13.3	%	
- any other impurity	≤ 5.0	< 5.0	%	
- total of other impurities	≤ 15.0	< 15.0	%	
Sulphate	27.0 – 31.0	28.2	%	dried substance
Loss on drying	≤ 8.0	2.1	%	3 h, 60°C, P ₂ O ₅ < 0.7 kPa,
Sulphated ash	≤ 1.0	0.07	%	
Assay	≥ 680	684	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: 08-03-2017

10- 

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