

**NEOMICINA SULFATO (EUR. PH.)**

PRODUCT CODE: 1324	CAS Nº: 1405-10-3	ANALYSIS Nº: 324/24
MANUFACTURER BATCH: 202402019	CERTIFICATE ID: 44.524	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 19/02/2024	
METAPH BATCH: 0111224	RETEST DATE: 18/02/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white powder, hygroscopic.	Yellowish-white powder, hygroscopic
Solubility	Very soluble in water, very slightly soluble in ethanol (96 %), practically insoluble in acetone.	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
pH	5.0 - 7.5	6.1
Specific optical rotation	+53.5 - +59.0	+58.2
Related substances		
Impurity A	=< 2.0 %	< 1.0 %
Impurity C	3.0 - 15.0 %	12.3 %
Any other impurity	=< 5.0 %	1.8 %
Total of other impurities	=< 15.0 %	2.9 %
Sulfates	27.0 - 31.0 %	27.5 %
Loss on drying	=< 8.0 %	6.8 %
Sulfated ash	=< 1.0 %	0.3 %
Assay	> 680 IU/mg	683 IU/mg

**COMPLIES WITH**

European Pharmacopeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Neomycin Sulfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(\*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.

**STORAGE**

Keep the container tightly closed and store it in a dry and cool place. Protect it from the light.

Analysis date: 20/02/2025  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000489  
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