

## NEOMICINA SULFATO (EUR. PH.)

PRODUCT CODE: 1324	CAS Nº: 1405-10-3	ANALYSIS Nº: 162/22
MANUFACTURER BATCH: 202110005	CERTIFICATE ID: 35.449	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 14/10/2021	
METAPH BATCH: 0160622	RETEST DATE: 13/10/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or yellowish-white powder, hygroscopic	Yellowish-white powder, hygroscopic
Solubility	Very soluble in water, very slightly soluble in alcohol, practically insoluble in acetone	Complies (*)
Identification A		
Limit impurity C	Complies	Complies
RT peak ref. sol. (e)	Complies	Complies
Identification B	Complies	Complies
pH	5.0 - 7.5	6.2
Specific optical rotation	+53.5 / +59.0	+ 53.7
Related substances		
Impurity A	=< 2.0 %	< 1.0 %
Impurity C	3.0 - 15.0 %	13.8 %
Any other impurity	=< 5.0 %	< 1.0 %
Total of other impurities	=< 15.0 %	< 1.0 %
Sulfates	27.0 - 31.0 %	27.8 %
Loss on drying	=< 8.0 %	4.2 %
Sulfated ash	=< 1.0 %	0.08 %
Assay	=> 680 IU/mg	708 IU/mg
Microbiological control		(*)
TAMC	=< 1000 CFU/g	< 10 UFC/g
TYMC	=< 100 CFU/g	< 10 UFC/g
Sodium bisulfite	=< 0.3 %	0.26 % (*)

### COMPLIES WITH

European Pharmacopoeia 10.3

### REMARKS

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

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.

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

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. The above information does not exempt from the obligation to identify the product before use.

### STORAGE

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

Analysis date: 12/09/2022

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000489

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