



## TECHNICAL DATA SHEET

1324-TDS-ENG-2023

NEOMICINA SULFATO (PH.EUR)		
DESCRIPTION DCI: NEOMYCIN SULFATE		DESCRIPTION DOE: NEOMICINA SULFATO
CAS Nº: 1405-10-3	EC Nº: 215-773-1	AEMPS CODE: 81SU
MOL. WEIGHT: 615.00	MOL. FORMULA: C <sub>23</sub> H <sub>48</sub> N <sub>6</sub> O <sub>17</sub> S	ARTICLE CODE: 1324

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

### COMPLIES WITH

European Pharmacopeia 11.0

### STORAGE

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

### 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.

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.