

TECHNICAL DATA SHEET

002961-TDS-ENG-2026

TOBRAMICINA SULFATO (USP)		
DESCRIPTION DCI: TOBRAMYCIN SULFATE		DESCRIPTION DOE: TOBRAMICINA SULFATO
CAS Nº: 79645-27-5	EC Nº: 616-717-2	AEMPS CODE: 3141SU
MOL. WEIGHT: 1425,42	MOL. FORMULA: (C ₁₈ H ₃₇ N ₅ O ₉) ₂ ·5H ₂ SO ₄	ARTICLE CODE: 002961

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder, hygroscopic.
Identification A	Complies
Identification B	Complies
Identification C	Complies
Assay	634 - 739 µg/mg
Residue on ignition	=< 1.0 %
Organic impurities	
Any other impurity	=< 1.0 %
pH	6.0 - 8.0
Water	=< 7.0 %
Microbiological control	
TAMC	< 1000 CFU/g
TYMC	< 100 CFU/g
E. Coli	Absence/1g
C. Albicans	Absence/1g
S. Aureus	Absence/1g
P. Aeruginosa	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

USP 2026

STORAGE

Preserve in tight containers at room temperature.

REMARKS

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