



TOBRAMICINA SULFATO (USP)

PRODUCT CODE: 002961	CAS Nº: 79645-27-5	ANALYSIS Nº: 218/24
MANUFACTURER BATCH: TB2401002	CERTIFICATE ID: 43.306	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 22/01/2024	
METAPH BATCH: 0010924	EXPIRY DATE: 21/01/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder, hygroscopic.	White powder, hygroscopic.
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Assay	634 - 739 µg/mg	721.6 µg/mg
Residue on ignition	=< 1.0 %	0.08 %
Organic impurities		
Any other impurity	=< 1.0 %	< 1.0 %
pH	6.0 - 8.0	7.4
Water	=< 7.0 %	0.7 %

COMPLIES WITH

USP 2024

REMARKS

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

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

All data controlled by Metapharmaceutical Industrial SL.

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.

STORAGE

Preserve in tight containers at room temperature.

Analysis date: 28/10/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000904