



TECHNICAL DATA SHEET

46433077-TDS-ENG-2024

PAROMOMICINA SULFATO (USP)		
DESCRIPTION DCI: PAROMOMYCIN SULFATE		DESCRIPTION DOE: PAROMOMICINA SULFATO
CAS N°: 1263-89-4	EC N°: 215-031-7	AEMPS CODE: 1002SU
MOL. WEIGHT: 615,63	MOL. FORMULA: C ₂₃ H ₄₅ N ₅ O ₁₄ nH ₂ SO ₄	ARTICLE CODE: 46433077

ATTRIBUTES	SHOULD BE
Appearance	White or white-yellowish fine powder
Identification A	Complies
Identification B	Complies
Specific rotation	+50° / +55°
pH	5.0 - 7.5
Loss on drying	<= 5.0 %
Residue on ignition	<= 2.0 %
Assay	>= 675 µg/mg

COMPLIES WITH

USP 2024

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Paromomycin Sulfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.