

PAROMOMICINA SULFATO (USP)

PRODUCT CODE: 46433077	CAS Nº: 1263-89-4	ANALYSIS Nº: 182/24
MANUFACTURER BATCH: 0024612001	CERTIFICATE ID: 42.883	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 26/05/2024	
METAPH BATCH: 0050724	RETEST DATE: 26/05/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or white-yellowish fine powder	White-yellowish fine powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Specific rotation	+50° / +55°	+54°
pH	5.0 - 7.5	6.1
Loss on drying	<= 5.0 %	2.4 %
Residue on ignition	<= 2.0 %	0.3 %
Assay	>= 675 µg/mg	775 µg/mg

COMPLIES WITH

USP 2024

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".

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

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

Analysis date: 02/08/2024
 Signature: Albert Sanchez Lopez (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000353

