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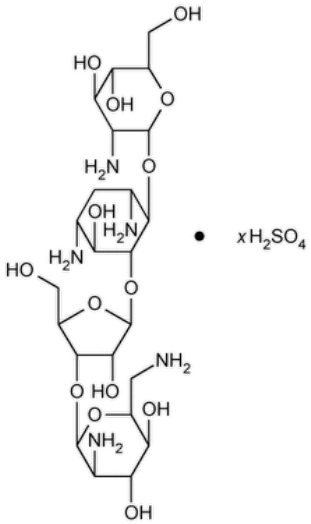
Paromomycin Sulfate



$C_{23}H_{45}N_5O_{14} \cdot xH_2SO_4$

D-Streptamine, [*O*-2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)-*O*-[*O*-2,6-diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-β-D-ribofuranosyl-(1→5)]-2-deoxy-, sulfate (salt).

O-2,6-Diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-*O*-β-D-ribofuranosyl-(1→5)-*O*-[2-amino-2-deoxy-α-D-glucopyranosyl-(1→4)]-2-deoxystreptamine sulfate (salt) CAS RN®: 1263-89-4; UNII: 845NU6GJPS.

Base

615.63 CAS RN®: 59-04-1; 7542-37-2; UNII: 61JJC8N5ZK.

» Paromomycin Sulfate is the sulfate salt of an antibiotic substance or substances produced by the growth of *Streptomyces rimosus* var. *paromomycinus*, or a mixture of two or more such salts. It has a potency equivalent to not less than 675 µg of paromomycin ($C_{23}H_{45}N_5O_{14}$) per mg, calculated on the dried basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Paromomycin Sulfate RS

Identification—

A: Prepare a test solution in water containing 10 mg of paromomycin per mL. Apply 25 µL of this solution and 25 µL of a Standard solution of USP Paromomycin Sulfate RS containing 10 mg of paromomycin per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel. Allow the spots to dry, place the plate in a developing chamber, and develop the chromatogram in a solvent system consisting of a mixture of freshly prepared ammonium acetate solution (4 in 100), *n*-propyl alcohol, and ammonium hydroxide (30:10:6) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and allow it to air-dry for 10 minutes. Heat the plate at 105° for 1 hour, allow to cool, and spray with a solution of ninhydrin in butanol (1 in 100). Heat the plate at 105° for 5 minutes: paromomycin appears as a red spot, and the R_F value of the principal spot obtained from the test solution corresponds to that obtained from the Standard solution.

B: It meets the requirements of the tests for *Sulfate* ⟨191⟩.

Specific rotation ⟨781S⟩: between +50° and +55°.

Test solution: 50 mg per mL, in water.

pH ⟨791⟩: between 5.0 and 7.5, in a solution (3 in 100).

Loss on drying ⟨731⟩—Dry about 100 mg in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 5.0% of its weight.

Residue on Ignition ⟨281⟩: not more than 2.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

Assay—Proceed with Paromomycin Sulfate as directed under *Antibiotics—Microbial Assays* ⟨81⟩.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PAROMOMYCIN SULFATE	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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