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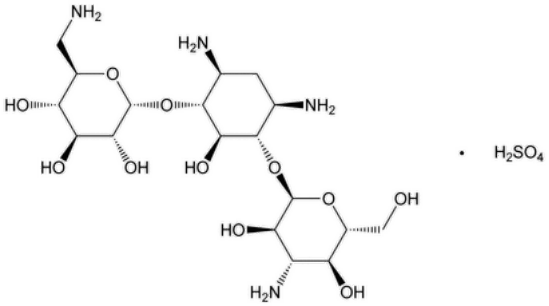
Kanamycin Sulfate



$C_{18}H_{36}N_4O_{11} \cdot H_2SO_4$ 582.58

D-Streptamine, *O*-3-amino-3-deoxy-α-D-glucopyranosyl(1→6)-*O*-[6-amino-6-deoxy-α-D-glucopyranosyl(1→4)]-2-deoxy-, sulfate (1:1) (salt); Kanamycin sulfate (1:1) (salt) CAS RN®: 25389-94-0; UNII: J80EX28SMQ.

DEFINITION

Kanamycin Sulfate has a potency equivalent to NLT 750 µg/mg of kanamycin ($C_{18}H_{36}N_4O_{11}$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

• **B.** Identification Tests—General, *Sulfate* ⟨191⟩**:** Meets the requirements

• **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Mobile phase: 0.115 N sodium hydroxide solution

System suitability solution: 20 µg/mL of USP Amikacin RS and 8 µg/mL of USP Kanamycin Sulfate RS in water

Standard solution: 8 µg/mL of USP Kanamycin Sulfate RS in water

Sample solution: 8 µg/mL of Kanamycin Sulfate in water

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: Pulsed amperometric electrochemical detector

Working electrode: Gold

Reference electrode: pH silver–silver chloride

Waveform: See *Table 1*.

Table 1

Time (s)	Potential (V)	Integration
0.00	+0.04	—
0.30	+0.04	Begin
0.50	+0.04	End
0.51	+0.80	—
0.70	+0.80	—

Time (s)	Potential (V)	Integration
0.71	−0.80	—
0.90	−0.80	—

Columns

Guard: 4-mm × 50-mm; 7.5-µm packing L47

Analytical: 4-mm × 25-cm; 7.5-µm packing L47

Flow rate: 0.5 mL/min

Injection volume: 20 µL

System suitability

[NOTE—The relative retention times for kanamycin and amikacin are about 1.0 and 1.3, respectively.]

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 3 between kanamycin and amikacin, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of kanamycin ($C_{18}H_{36}N_4O_{11}$) in the portion of Kanamycin Sulfate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P$$

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Kanamycin Sulfate RS in the *Standard solution* (µg/mL)

C_U = concentration of Kanamycin Sulfate in the *Sample solution* (µg/mL)

P = potency of kanamycin in USP Kanamycin Sulfate RS (µg/mg)

Acceptance criteria: NLT 750 µg/mg on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩**

Analysis: Moisten the charred residue with 2 mL of nitric acid and 5 drops of sulfuric acid.

Acceptance criteria: NMT 1.0%

• **ORGANIC IMPURITIES**

Adsorbent: 0.25-mm layer of chromatographic silica gel

Developing solvent system: 75 mg/mL of monobasic potassium phosphate in water

Spray reagent: 10 mg/mL of ninhydrin in butyl alcohol

Standard solution 1: 30 mg/mL of USP Kanamycin Sulfate RS in water

Standard solution 2: 0.90 mg/mL of USP Kanamycin Sulfate RS in water

Sample solution: 30 mg/mL of Kanamycin Sulfate in water

Application volume: 1 µL

Analysis: Heat the plate at 110° for 1 h immediately before use, and allow it to cool. Equilibrate for 90 min with the *Developing solvent system*. Apply all three solutions to the plate separately, allow the spots to dry, and develop the chromatogram with the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the chamber, and air-dry. Spray the plate with *Spray reagent*. Dry the plate at 110° for 10 min, and examine the chromatograms.

Acceptance criteria: The chromatograms show principal spots at the same R_F value, and no secondary spot, if present from the *Sample solution*, is more intense than the principal spot of *Standard solution 2*.

SPECIFIC TESTS

• **CRYSTALLINITY ⟨695⟩:** Meets the requirements

• **pH ⟨791⟩**

Sample solution: 10 mg/mL

Acceptance criteria: 6.5–8.5

• **LOSS ON DRYING ⟨731⟩**

Analysis: Dry 100 mg in a vacuum in a capillary-stoppered bottle at a pressure not exceeding 5 mm of mercury at 60° for 3 h.

Acceptance criteria: NMT 4.0%

• **Sterility Tests ⟨71⟩:** Where the label states that Kanamycin Sulfate is sterile, it meets the requirements when tested as directed for membrane filtration in *Test for Sterility of the Product to Be Examined*.

• **Bacterial Endotoxins Test ⟨85⟩:** Where the label states that Kanamycin Sulfate must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.67 USP Endotoxin Unit/mg of Kanamycin.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

• **USP Reference Standards ⟨11⟩**

USP Amikacin RS

USP Kanamycin Sulfate RS

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

Topic/Question	Contact	Expert Committee
KANAMYCIN SULFATE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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