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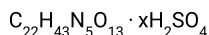
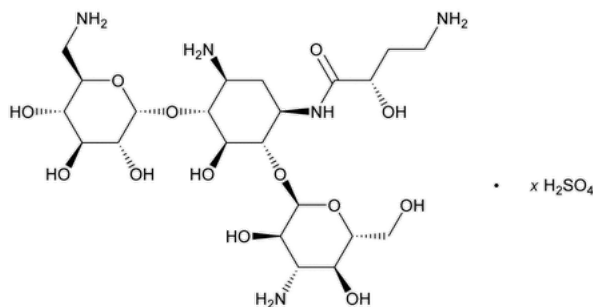
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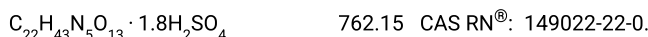
Amikacin Sulfate



D-Streptamine, O-3-amino-3-deoxy-α-D-glucopyranosyl-(1→6)-O-[6-amino-6-deoxy-α-D-glucopyranosyl-(1→4)]-N¹-(4-amino-2-hydroxy-1-oxobutyl)-2-deoxy-, (S)-, sulfate (1:2 or 1:1.8 salt);

O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→4)-O-[6-amino-6-deoxy-α-D-glucopyranosyl-(1→6)]-N³-(4-amino-L-2-hydroxybutyryl)-2-deoxy-D-streptamine sulfate (1:2 or 1:1.8 salt);

(2S)-4-Amino-N-[(1R,2S,3S,4R,5S)-5-amino-2-[(3-amino-3-deoxy-α-D-glucopyranosyl)oxy]-4-[(6-amino-6-deoxy-α-D-glucopyranosyl)oxy]-3-hydroxycyclohexyl]-2-hydroxybutanamide sulfate (1:2 or 1:1.8 salt).



DEFINITION

Amikacin Sulfate having a molar ratio of amikacin to sulfuric acid (H_2SO_4) of 1:2 contains the equivalent of NLT 674 µg/mg and NMT 786

µg/mg of amikacin ($\text{C}_{22}\text{H}_{43}\text{N}_5\text{O}_{13}$), calculated on the dried basis. Amikacin Sulfate having a molar ratio of amikacin to sulfuric acid (H_2SO_4) of 1:1.8 contains the equivalent of NLT 691 µg/mg and NMT 806 µg/mg of amikacin ($\text{C}_{22}\text{H}_{43}\text{N}_5\text{O}_{13}$), calculated on the dried basis.

IDENTIFICATION

- A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A

Acceptance criteria: The IR absorption spectrum conforms to that of [USP Amikacin Sulfate RS](#), similarly obtained.

- B.** The retention time of the peak for amikacin of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- C. IDENTIFICATION TESTS—GENERAL (191), Chemical Identification Tests, Sulfate:** Meets the requirements

ASSAY

Change to read:

PROCEDURE

Mobile phase: 134 mM [sodium hydroxide](#), prepared as follows. Transfer a volume of deionized water to a suitable plastic container, sonicate, degas, and sparge with helium. While stirring, slowly add sodium hydroxide solution of a suitable concentration.

[NOTE—Prepare fresh daily. The *Mobile phase* readily absorbs carbon dioxide and produces carbonate that changes the retention time of amikacin. The use of a 50% (w/w), low-carbonate sodium hydroxide solution is recommended.]

System suitability solution: 0.02 mg/mL of [USP Amikacin RS](#) and 0.008 mg/mL of [USP Kanamycin Sulfate RS](#) in water

Standard solution: 0.02 mg/mL of [USP Amikacin RS](#) in water

Sample solution: Equivalent to 0.02 mg/mL of amikacin, from Amikacin Sulfate, in water

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Electrochemical

Mode: Integrated amperometric

Electrodes

Working: Gold

Reference: Silver–silver chloride

Detector settings: See [Table 1](#).

Table 1

Step	Time (s)	Potential (V)	Integration
1	0.00	+0.04	—
2	0.30	+0.04	Begins
3	0.50	+0.04	Ends
4	0.51	+0.80	—
5	0.70	+0.80	—
6	0.71	-0.80	—
7	0.90	-0.80	—

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

[NOTE—A guard column of packing L47 is recommended.]

Flow rate: 0.5 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—The relative retention times for kanamycin and amikacin are 0.8 and 1.0, respectively.]

Suitability requirements

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

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 3%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in μg, of amikacin ($C_{22}H_{43}N_5O_{13}$) in each mg of Amikacin Sulfate taken:

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

r_U = peak response of amikacin from the *Sample solution*

r_S = peak response of amikacin from the *Standard solution*

C_S = concentration of [USP Amikacin RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of ▲ Amikacin Sulfate▲ (ERR 1-Dec-2023) in the *Sample solution* (mg/mL)

P = potency of amikacin in [USP Amikacin RS](#) (mg/mg)

F = conversion factor, 1000 μg/mg

Acceptance criteria: See [Table 2](#).

Table 2

Ratio of Amikacin:Sulfuric Acid	Acceptance Criteria (μg/mg) ^a
1:2	674–786
1:1.8	691–806

^a Calculated on the dried basis.

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 1.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.