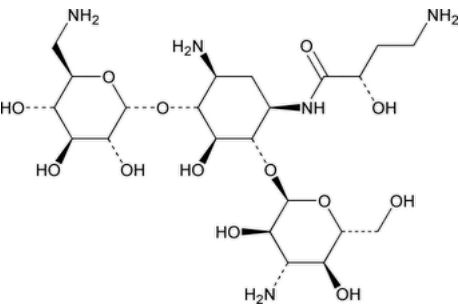


Status: Currently Official on 13-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-5BE69D81-FAA4-4AC4-B3C8-E6A68713ADB8_4_en-US
DOI: https://doi.org/10.31003/USPNF_M2610_04_01
DOI Ref: zc6u6

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Amikacin



C₂₂H₄₃N₅O₁₃ 585.60

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)-;

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-L-streptamine CAS RN®: 37517-28-5; UNII: 84319SGC3C.

DEFINITION

Amikacin has a potency of NLT 900 µg/mg of amikacin (C₂₂H₄₃N₅O₁₃), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲[SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197K or 197A▲ (CN 1-May-2020)
- **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.

ASSAY

• 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: 0.02 mg/mL of Amikacin 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

Step	Time (s)	Potential (V)	Integration
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 (C₂₂H₄₃N₅O₁₃) in each mg of Amikacin 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 in the *Sample solution* (mg/mL)

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

F = conversion factor, 1000 μg/mg

Acceptance criteria: NLT 900 μg/mg on the anhydrous 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

SPECIFIC TESTS

- [OPTICAL ROTATION \(781S\)](#), [Procedures](#), [Specific Rotation](#)

Sample solution: 20 mg/mL in water

Acceptance criteria: +97° to +105°

- [CRYSTALLINITY \(695\)](#): Meets the requirements

- [pH \(791\)](#)

Sample solution: 10 mg/mL in water

Acceptance criteria: 9.5–11.5

- [WATER DETERMINATION \(921\)](#), [Method I](#): NMT 8.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Amikacin RS](#)

[USP Kanamycin Sulfate RS](#)

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 42(6)

Current DocID: GUID-5BE69D81-FAA4-4AC4-B3C8-E6A68713ADB8_4_en-US

DOI: https://doi.org/10.31003/USPNF_M2610_04_01

DOI ref: [zc6u6](#)

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