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Amikacin Sulfate Injection

DEFINITION

Amikacin Sulfate Injection is a sterile solution of Amikacin Sulfate in Water for Injection, or of Amikacin in Water for Injection prepared with the aid of Sulfuric Acid. It contains NLT 90.0% and NMT 120.0% of the labeled amount of amikacin ($C_{22}H_{43}N_5O_{13}$).

IDENTIFICATION

• **A.** 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

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.]

▲*USP41*

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: Nominally 0.02 mg/mL of amikacin, from Injection in water

Chromatographic system

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

Mode: LC

Detector: Electrochemical

Detector 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.]

▲*USP41*

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 percentage of ▲the labeled amount of▲*USP41* amikacin ($C_{22}H_{43}N_5O_{13}$) in ▲the portion▲*USP41* of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times 100$$

r_U = peak ▲response of amikacin▲*USP41* from the *Sample solution*

r_S = peak ▲response of amikacin▲*USP41* from the *Standard solution*

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

C_U = nominal concentration of amikacin in the *Sample solution*▲(mg/mL)▲ (ERR 1-Sep-2018)

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

Acceptance criteria: 90.0%–120.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 3.5–5.5
- **PARTICULATE MATTER IN INJECTIONS ⟨788⟩:** Meets the requirements for small-volume injections
- **BACTERIAL ENDOTOXINS TEST ⟨85⟩:** NMT 0.33 USP Endotoxin Units/mg of amikacin
- **OTHER REQUIREMENTS:** Meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type III glass.

Change to read:

- **USP REFERENCE STANDARDS ⟨11⟩**

USP Amikacin RS

▲▲ (CN 1-May-2018)

USP Kanamycin Sulfate RS

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

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

Chromatographic Database Information: Chromatographic Database

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