Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-93FB5E9E-2F08-4CA3-B7CF-A84823D86B74_3_en-US
DOI: https://doi.org/10.31003/USPNF_M43828_03_01
DOI Ref: 5i51v

Kanamycin Injection

DEFINITION

Kanamycin Injection contains an amount of kanamycin sulfate equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of kanamycin ($C_{18}H_{36}N_4O_{11}$). It contains suitable buffers and preservatives.

IDENTIFICATION

• **A.** **Thin-Layer Chromatographic Identification Test ⟨201⟩**

Sample solution: 1 mg/mL of kanamycin from Injection in water

Chromatographic system

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture, heated at 110° for 1 h and cooled immediately before use

Application volume: 10 µL

Developing solvent system: 150 mg/mL of monobasic potassium phosphate in water

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

Analysis: Proceed as directed in the chapter. Allow the spots to dry, and develop in a chamber previously equilibrated for 18 h with the *Developing solvent system*. Remove the plate from the chamber, and air-dry. Spray the plate with *Spray reagent*, and dry at 110° for 10 min.

Acceptance criteria: Meets the requirements

• **B.** The retention time of the kanamycin 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: Nominally 6 µg/mL of kanamycin from Injection in water

Chromatographic system

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

Mode: LC

Detector: Electrochemical

Mode: Integrated amperometric

Range: 300 nC

Output: 1 V full-scale

Electrodes

Indicator: Gold

Reference: 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

Time (s)	Potential (V)	Integration
0.51	+0.80	—
0.70	+0.80	—
0.71	−0.80	—
0.90	−0.80	—

Columns

Guard: Packing L47

Analytical: 4-mm × 25-cm; packing L47

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 about 1.0 and 1.3, respectively.]

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 percentage of the labeled amount of kanamycin ($C_{18}H_{36}N_4O_{11}$) in the portion of Injection taken:

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

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 = nominal concentration of kanamycin in the *Sample solution* (µg/mL)

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

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 3.5–5.0
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.67 USP Endotoxin Unit/mg of kanamycin
- **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I or Type III glass.
- **USP Reference Standards ⟨11⟩**

USP Amikacin RS

USP Kanamycin Sulfate RS

Topic/Question	Contact	Expert Committee
KANAMYCIN INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 26(6)

Current DocID: GUID-93FB5E9E-2F08-4CA3-B7CF-A84823D86B74_3_en-US
Previous DocID: GUID-93FB5E9E-2F08-4CA3-B7CF-A84823D86B74_1_en-US
DOI: https://doi.org/10.31003/USPNF_M43828_03_01
DOI ref: 5i51v