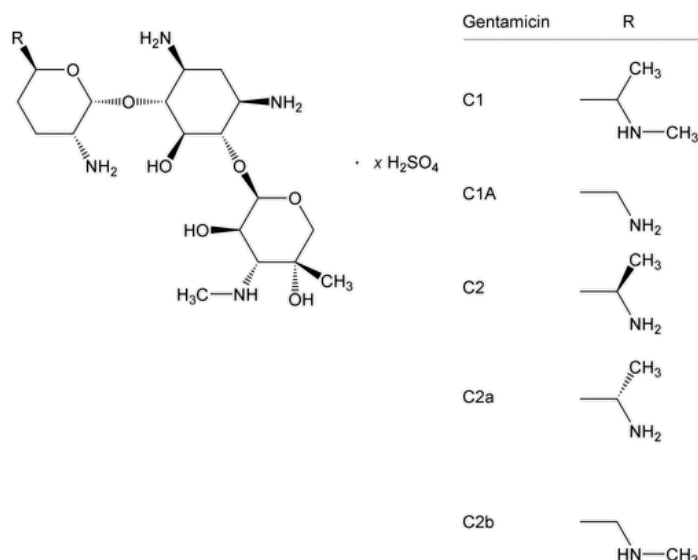


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Gentamicin Sulfate



Gentamicin sulfate (salt);

Gentamycin sulfate

CAS RN[®]: 1405-41-0; UNII: 8X7386QRLV.

DEFINITION

Gentamicin Sulfate is the sulfate salt, or a mixture of such salts, of the antibiotic substances produced by the growth of *Micromonospora purpurea*. It has a potency equivalent to NLT 590 µg/mg of gentamicin, 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 \(191\).](#)

ASSAY

• PROCEDURE

Analysis: Proceed as directed for Gentamicin under [Antibiotics—Microbial Assays \(81\)](#).

Acceptance criteria: NLT 590 µg/mg of gentamicin, calculated on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 1.0%
- **LIMIT OF METHANOL** (if present)

Internal standard solution: 0.50% v/v of *n*-propyl alcohol

Standard solution: 0.25% v/v each of methanol and *n*-propyl alcohol

Control solution: 250 mg/mL of Gentamicin Sulfate

Sample solution: 250 mg/mL of Gentamicin Sulfate in a mixture of *Internal standard solution* and water (1:1)

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 4-mm × 1.5-m; packed with support S3

Temperature

Column: Constant temperature between 120° and 140°

Injector: Constant temperature at least 50° higher than the column temperature

Detector: Constant temperature at least 50° higher than the column temperature

Carrier gas: Nitrogen

Flow rate: Constant flow rate between 30 and 40 mL/min

Injection type: Syringe with a polytetrafluoroethylene-tipped plunger

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 1.0 between *n*-propyl alcohol and methanol

Analysis

Samples: *Standard solution*, *Sample solution*, and *Control solution*

Chromatograph the *Control solution*, and examine the chromatogram: if any peak is observed at a retention time corresponding to that of *n*-propyl alcohol, use the response of that peak to correct the *n*-propyl alcohol peak response of the *Sample solution*.

Calculate the percentage of methanol in the Gentamicin Sulfate taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times D \times F$$

R_U = peak area response of methanol to *n*-propyl alcohol (corrected for any peak at the locus of the *n*-propyl alcohol peak in the *Control solution*) from the *Sample solution*

R_S = peak area response of methanol to *n*-propyl alcohol from the *Standard solution*

C_S = percentage of methanol in the *Standard solution*

C_U = concentration of Gentamicin Sulfate in the *Sample solution* (mg/mL)

D = density of methanol (g/mL)

F = conversion factor, 1000 mg/g

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

• **CONTENT OF GENTAMICINS**

Mobile phase: To 900 mL of carbonate-free water, add 7 mL of trifluoroacetic acid, 250 µL of pentafluoropropanoic acid, and 4 mL of 12.5 M sodium hydroxide (carbonate-free). Allow to equilibrate, and adjust with 0.5 M sodium hydroxide (carbonate-free) to a pH of 2.6. Add 15 mL of acetonitrile, and dilute with carbonate-free water to 1 L. If necessary, adjust the volume of acetonitrile in the *Mobile phase*. A total volume of up to 50 mL can be added per L of *Mobile phase*.

System suitability solution: 100 µg/mL of [USP Gentamicin Sulfate RS](#) and 20 µg/mL of [USP Sisomicin Sulfate RS](#) in *Mobile phase*

Sample solution: 0.2 mg/mL of Gentamicin Sulfate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Pulsed amperometric electrochemical detector

Indicator electrode: Gold

Reference electrode: Silver–silver chloride

Auxiliary electrode: Stainless steel. [NOTE—If the cell body is made of stainless steel, it can be used as the auxiliary electrode.]

Waveform: See [Table 1](#).

Table 1

Time (s)	Potential (V)	Integration
0.00	+0.05	
0.10	+0.05	



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