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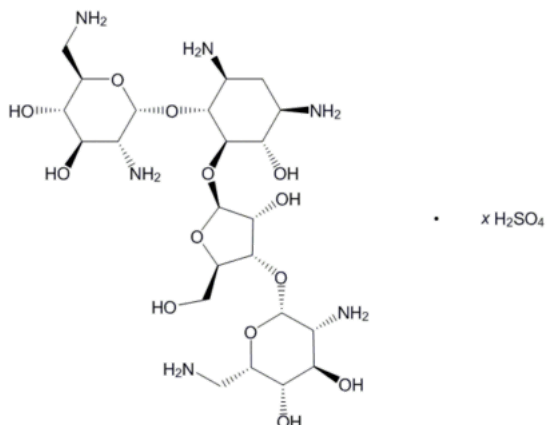
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Neomycin Sulfate

Change to read:



▲ $C_{23}H_{46}N_6O_{13}$ (free base) 614.65 (free base)

Neomycin B

2-Deoxy-4-O-(2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl)-5-O-[3-O-(2,6-diamino-2,6-dideoxy-β-L-idopyranosyl)-β-D-ribofuranosyl]-D-streptamine (free base) CAS RN®: 119-04-0.▲ (USP 1-Aug-2023)

Neomycin sulfate CAS RN®: 1405-10-3; UNII: 057Y626693.

Change to read:

DEFINITION

Neomycin Sulfate is the sulfate salt of a kind of neomycin, an antibacterial substance produced by the growth of *Streptomyces fradiae*

Waksman (Fam. Streptomycetaceae), or a mixture of two or more such salts▲, the main component being neomycin B sulfate.▲ (USP 1-Aug-2023) It has a potency equivalent to NLT 600 µg of neomycin/mg, calculated on the dried basis.

IDENTIFICATION

- A. It meets the requirements for neomycin under [Thin-Layer Chromatographic Identification Test \(201BNP\)](#).

Change to read:

- B.

▲**Mobile phase, System suitability solution, Sensitivity solution, Standard solution, Chromatographic system, and System suitability:** Proceed as directed in the test for *Composition of Neomycin Sulfate*.

Sample identification solution: 0.025 mg/mL of Neomycin Sulfate in *Mobile phase*

Acceptance criteria: The retention time of the neomycin B peak of the *Sample identification solution* corresponds to that of the *Standard solution*, as obtained in the test for *Composition of Neomycin Sulfate*.▲ (USP 1-Aug-2023)

- C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Sulfate](#)

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**

(See [Antibiotics—Microbial Assays \(81\)](#).)

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NLT 600 µg of neomycin/mg on the dried basis

Add the following:

▲IMPURITIES

- **ORGANIC IMPURITIES**

Mobile phase, System suitability solution, Sensitivity solution, Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the test for *Composition of Neomycin Sulfate*.

Analysis**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Neomycin Sulfate taken:

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

 r_U = peak response of each individual impurity from the *Sample solution* r_S = peak response of neomycin B from the *Standard solution* C_S = concentration of [USP Neomycin B RS](#) in the *Standard solution* (mg/mL) C_U = concentration of neomycin sulfate in the *Sample solution* (mg/mL)**Acceptance criteria:** See [Table 1](#). The reporting threshold is 1.0%.**Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Neomycin B-LP ^a	1.1	—
Any individual unspecified impurity	—	5.0
Total unspecified impurities	—	15.0

^a 3-*N*-Acetyl-2-deoxy-4-*O*-(2,6-diamino-2,6-dideoxy- α -D-glucopyranosyl)-5-*O*-[3-*O*-(2,6-diamino-2,6-dideoxy- β -L-idopyranosyl)- β -D-ribofuranosyl]-D-streptamine.

▲ (USP 1-Aug-2023)

SPECIFIC TESTS**Add the following:****▲ • COMPOSITION OF NEOMYCIN SULFATE****Mobile phase:** 20 mL of [trifluoroacetic acid](#), 6 mL of [50% sodium hydroxide TS](#), and 500 mL of [water](#), diluted with [water](#) to 1000 mL**System suitability solution:** 0.1 mg/mL of [USP Neomycin Sulfate System Suitability Mixture RS](#) (contains neomycin B and neomycin C) in *Mobile phase***Sensitivity solution:** 0.005 mg/mL of [USP Neomycin B RS](#) in *Mobile phase***Standard solution:** 0.025 mg/mL of [USP Neomycin B RS](#) and 0.01 mg/mL of [USP Neomycin A RS](#) in *Mobile phase***Sample solution:** 0.5 mg/mL of Neomycin Sulfate in *Mobile phase***Chromatographic system**(See [Chromatography \(621\), System Suitability](#).)**Mode:** LC**Detector:** Pulsed amperometric electrochemical**Electrodes****Indicator:** Gold**Reference:** Silver–silver chloride**Auxiliary:** Stainless steel (cell body)**Waveform:** See [Table 2](#).**Table 2**

Time (s)	Potential (V)	Integration
0.00	+0.00	—
0.10	+0.00	Begin
0.40	+0.00	End
0.41	+0.80	