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Capreomycin for Injection

DEFINITION

Capreomycin for Injection contains an amount of Capreomycin Sulfate equivalent to NLT 90.0% and NMT 115.0% of the labeled amount of capreomycin.

IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL, Sulfate\(191\)](#).
- **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *System suitability solution*, as obtained in the test for *Capreomycin 1 Content*.

ASSAY

- **PROCEDURE:** Proceed as directed in [Antibiotics—Microbial Assays \(81\)](#).
- Acceptance criteria:** 90.0%–115.0%

IMPURITIES

INORGANIC IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 3.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid

SPECIFIC TESTS

• CAPREOMYCIN 1 CONTENT

Solution A: 0.4 mg/mL of ammonium bisulfate in water. Pass through a filter of 0.5-µm or less pore size.

Mobile phase: Methanol and *Solution A* (2:3)

System suitability solution: 0.25 mg/mL of [USP Capreomycin Sulfate RS](#) in water

Sample solution: 0.25 mg/mL of Capreomycin for Injection in water

Chromatographic system

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

Mode: LC

Detector: UV 268 nm

Column: 4.6-mm × 25-cm; 5-µm packing L10

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times of capreomycin 1A and capreomycin 1B are 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between capreomycin 1A and capreomycin 1B

Tailing factor: NMT 3.5 for the major peaks (capreomycin 1A and capreomycin 1B)

Analysis

[NOTE—The chromatographic run time is at least five times the retention time of the capreomycin 1A peak.]

Sample: *Sample solution*

Calculate the percentage of capreomycin 1 in the portion of Capreomycin for Injection taken:

$$\text{Result} = (r_{1A} + r_{1B})/r_T \times 100$$

r_{1A} = peak area response for capreomycin 1A

r_{1B} = peak area response for capreomycin 1B

r_T = total response for all peaks

Acceptance criteria: The capreomycin 1 content is NLT 90.0%.

- [pH \(791\)](#): 4.5–7.5

Sample solution: 30 mg/mL

- **LOSS ON DRYING (731):** Dry 100 mg in a vacuum at a pressure not exceeding 5 mm of mercury at 100° for 4 h: it loses NMT 10.0% of its weight.
- **BACTERIAL ENDOTOXINS TEST (85):** NMT 0.35 USP Endotoxin Unit/mg of capreomycin
- **CONSTITUTED SOLUTION:** At the time of use, it meets the requirements for [Injections and Implanted Drug Products \(1\)](#), [Specific Tests, Completeness and clarity of solutions](#).
- **OTHER REQUIREMENTS:** It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging, Packaging for constitution](#).
- **USP REFERENCE STANDARDS (11).**
[USP Capreomycin Sulfate RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CAPREOMYCIN FOR INJECTION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

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