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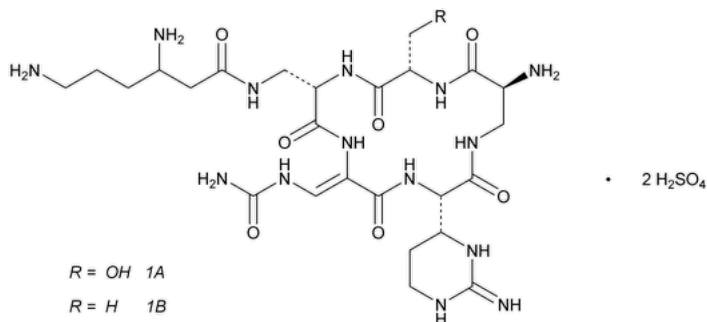
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Capreomycin Sulfate



Capreomycin sulfate CAS RN®: 1405-37-4; UNII: 9H8D3J7V21. $\text{C}_{25}\text{H}_{44}\text{N}_{14}\text{O}_8$ 668.71

Capreomycin 1A (free base);

3,6-Diamino-*N*-{[(2*S*,5*S*,11*S*,15*S*,*Z*)-15-amino-2-(hydroxy methyl)-11-[(*R*)-iminohexahydropyrimidin-4-yl]-3,6,9,12,16-pentaoxo-8-(ureidomethylene)-1,4,7,10,13-pentaazacyclohexadecan-5-yl)methyl}hexanamide CAS RN®: 37290-35-6.

$\text{C}_{25}\text{H}_{44}\text{N}_{14}\text{O}_7$ 652.71

Capreomycin 1B (free base);

3,6-Diamino-*N*-{[(2*S*,5*S*,11*S*,15*S*,*Z*)-15-amino-11-[(*R*)-iminohexahydropyrimidin-4-yl]-2-methyl-3,6,9,12,16-pentaoxo-8-(ureidomethylene)-1,4,7,10,13-pentaazacyclohexadecan-5-yl)methyl}hexanamide CAS RN®: 33490-33-4; UNII: 2YP3RYC823.

DEFINITION

Capreomycin Sulfate is the disulfate salt of capreomycin, a polypeptide mixture produced by the growth of *Streptomyces capreolus*, suitable for parenteral use. It has a potency equivalent to NLT 700 µg/mg and NMT 1050 µg/mg 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: 700–1050 µg/mg

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 Sulfate 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 Sulfate taken:

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

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

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

r_T = total response for all peaks

Acceptance criteria: 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):** Where it is intended for use in preparing injectable dosage forms: NMT 0.35 USP Endotoxin Unit/mg of capreomycin
- **OTHER REQUIREMENTS:** Where the label states that Capreomycin Sulfate is sterile, it meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.
- **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 SULFATE	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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