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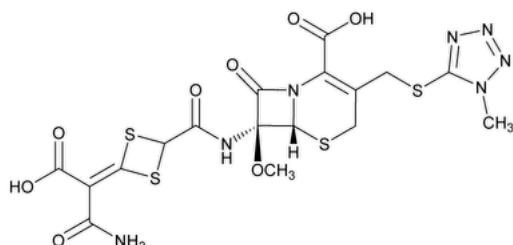
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Cefotetan


 $C_{17}H_{17}N_7O_8S_4$ 575.62

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[4-(2-amino-1-carboxy-2-oxoethylidene)-1,3-dithietan-2-yl]carbonyl]amino]-7-methoxy-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-, [6R-(6α,7α)]-;

(6R,7S)-4-[[[2-Carboxy-7-methoxy-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-7-yl]carbonyl]-1,3-dithietane-Δ^{2,α}-malonamic acid;

(6R,7S)-7-[4-(Carbamoylcarboxymethylene)-1,3-dithietane-2-carboxamido]-7-methoxy-3-[[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid CAS RN[®]: 69712-56-7; UNII: 48SPP0PA9Q.

DEFINITION

Cefotetan contains NLT 950 µg/mg and NMT 1030 µg/mg of cefotetan ($C_{17}H_{17}N_7O_8S_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** **▲** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#)▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Protect the *Standard solution*, the *System suitability solution*, and the *Sample solution* from light, and use within 2 h.

Mobile phase: Methanol, acetonitrile, glacial acetic acid, and 0.1 M phosphoric acid (105:105:100:1700)

Standard solution: 0.2 mg/mL of [USP Cefotetan RS](#) in methanol, acetonitrile, and water (5:5:90), prepared as follows. Place a suitable quantity of [USP Cefotetan RS](#) in a suitable volumetric flask, and add methanol, using 5% of the final volume. Swirl for several min, and add acetonitrile, using 5% of the final volume. Swirl until dissolved, and dilute with water to volume.

System suitability solution: Transfer 10 mL of *Standard solution* to a glass-stoppered flask containing a few mg of magnesium carbonate. Sonicate for 10 min. If the solution is not turbid, add a few more mg of magnesium carbonate, and repeat the sonication. Pass the turbid solution through a filter of 0.5-µm or finer pore size. Use the clear filtrate.

Sample solution: 0.2 mg/mL of Cefotetan in methanol, acetonitrile, and water (5:5:90), prepared as follows. Place a suitable quantity of Cefotetan in a suitable volumetric flask, and add methanol, using 5% of the final volume. Swirl for several min, and add acetonitrile, using 5% of the final volume. Swirl until dissolved, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—The relative retention times for cefotetan and cefotetan tautomer are 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between cefotetan and cefotetan tautomer, *System suitability solution*

Column efficiency: NLT 1500 theoretical plates, *Standard solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefotetan (C₁₇H₁₇N₇O₈S₄) in the portion of Cefotetan taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Cefotetan RS](#) in the *Standard solution* (mg/mL)

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

P = potency of cefotetan in [USP Cefotetan RS](#) (µg/mg)

Acceptance criteria: 950–1030 µg/mg on the anhydrous basis

SPECIFIC TESTS

- **STERILITY TESTS** (71): Where the label states that Cefotetan is sterile, it meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*, except use *Fluid A* to each 1000 mL of which has been added 10 g of sodium bicarbonate before sterilization.
- **BACTERIAL ENDOTOXINS TEST** (85): Where the label states that Cefotetan is sterile or must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.17 USP Endotoxin Unit/mg of cefotetan.
- **WATER DETERMINATION, Method I** (921): NMT 2.5%

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 Cefotetan RS](#)

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

Topic/Question	Contact	Expert Committee
CEFOTETAN	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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