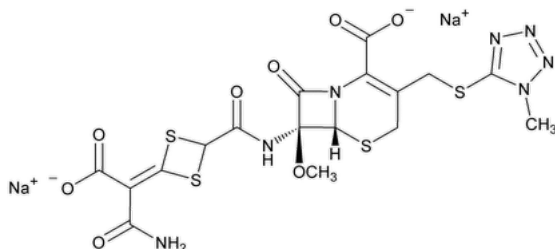


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Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefotetan (C₁₇H₁₇N₇O₈S₄) in the portion of Cefotetan Disodium 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 Disodium in the *Sample solution* (mg/mL)

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

Acceptance criteria: 830–970 µg/mg on the anhydrous basis

SPECIFIC TESTS

• [pH \(791\)](#)

Sample solution: 100 mg/mL

Acceptance criteria: 4.0–6.5

• [WATER DETERMINATION, Method Ic \(921\)](#): NMT 2.5%

• [STERILITY TESTS \(71\)](#): Where the label states that Cefotetan Disodium is sterile, it meets the requirements when tested as directed for [Test for Sterility of the Product to Be Examined, Membrane Filtration](#).

• [BACTERIAL ENDOTOXINS TEST \(85\)](#): Where the label states that Cefotetan Disodium is sterile or it must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.17 USP Endotoxin Unit/mg of cefotetan.

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 DISODIUM	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 43(6)

Current DocID: GUID-79B05963-29DF-49DE-8A62-20A164157A0C_3_en-US

Previous DocID: GUID-79B05963-29DF-49DE-8A62-20A164157A0C_1_en-US

DOI: https://doi.org/10.31003/USPNF_M14096_03_01

DOI ref: [g9nz6](#)