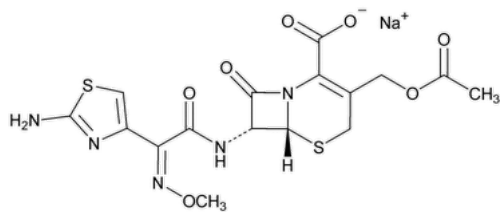


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Cefotaxime Sodium



$C_{16}H_{16}N_5NaO_7S_2$ 477.45
5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[(acetyloxy)methyl]-7-[[[(2-amino-4-thiazolyl)(methoxyimino)acetyl]amino]-8-oxo-, monosodium salt, [6R-[6 α ,7 β (Z)]]-;
Sodium (6R,7R)-7-[2-(2-amino-4-thiazolyl)glyoxylamido]-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate 7²-(Z)-(O-methyloxime), acetate (ester) CAS RN[®]: 64485-93-4; UNII: 258J72S7TZ.

DEFINITION

Cefotaxime Sodium contains the equivalent of NLT 916 µg/mg and NMT 964 µg/mg of cefotaxime ($C_{16}H_{17}N_5O_7S_2$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (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.
- **C.** [IDENTIFICATION TESTS—GENERAL, Sodium \(191\)](#): It meets the requirements.

ASSAY

• **PROCEDURE**

Buffer: 7.1 g/L of anhydrous dibasic sodium phosphate in water. Adjust with phosphoric acid to a pH of 6.25.

Solution A: Methanol and *Buffer* (14:86)

Solution B: Methanol and *Buffer* (40:60)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
7	100	0
9	80	20
16	80	20
45	0	100
50	0	100
55	100	0
65	100	0

System suitability stock solution: 0.08 mg/mL each of [USP Cefetamet RS](#) and [USP Cefotaxime Related Compound E RS](#) prepared as follows. Dissolve [USP Cefetamet RS](#) and [USP Cefotaxime Related Compound E RS](#) in the minimum volume of methanol. Sonicate, if necessary, and

dilute with *Solution A* to volume.

System suitability solution: 8 µg/mL each of cefetamet and cefotaxime related compound E from *System suitability stock solution* in *Solution A*. Store refrigerated, and use within 24 h.

Standard solution: 0.8 mg/mL of [USP Cefotaxime Sodium RS](#) in *Solution A*. Store refrigerated, and use within 24 h.

Sensitivity solution: 1.6 µg/mL of [USP Cefotaxime Sodium RS](#) from the *Standard solution* in *Solution A*. Store refrigerated, and use within 24 h.

Sample solution: 0.8 mg/mL of Cefotaxime Sodium in *Solution A*. Store refrigerated, and use within 24 h.

Chromatographic system

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

Mode: LC

Detector: UV 235 nm

Column: 3.9-mm × 15-cm; 5-µm packing L1

Temperatures

Column: 30°

Autosampler: 4°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cefetamet and cefotaxime related compound E, *System suitability solution*

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Sensitivity: Calculate the peak response ratio:

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

r_U = peak response from the *Sensitivity solution*

r_S = peak response from the *Standard solution*

Acceptance criteria: 0.18%–0.22%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefotaxime ($C_{16}H_{17}N_5O_7S_2$) in the portion of Cefotaxime Sodium 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 Cefotaxime Sodium RS](#) in the *Standard solution* (mg/mL)

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

P = potency of cefotaxime in [USP Cefotaxime Sodium RS](#) (µg/mg)

Acceptance criteria: 916–964 µg/mg on the dried basis

IMPURITIES

• ORGANIC IMPURITIES, PROCEDURE 1

Use *Organic Impurities, Procedure 1*, when the impurity profile includes *N*-formyl cefotaxime and cefotaxime dioxime.

Buffer, Solution A, Solution B, Mobile phase, System suitability solution, Sensitivity solution, Standard solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Cefotaxime Sodium taken:

$$\text{Result} = [r_U/(r_T + r_C)] \times 100$$

r_U = peak response of each individual impurity

r_T = sum of all of the impurity peak responses