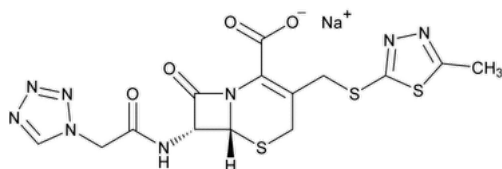


Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-E4ADA5DD-C2CC-4E87-AA78-3F89E68E937E_6_en-US
 DOI: https://doi.org/10.31003/USPNF_M13972_06_01
 DOI Ref: 03iki

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Cefazolin Sodium



$C_{14}H_{13}N_8NaO_4S_3$ 476.49

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[[[(1H-tetrazol-1-yl)acetyl]amino]-, monosodium salt (6R-trans)-;

Monosodium (6R,7R)-3-[[[(5-methyl-1,3,4-thiadiazol-2-yl)thio]methyl]-8-oxo-7-[2-(1H-tetrazol-1-yl)acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate; CAS RN®: 27164-46-1; UNII: P380M0454Z.

DEFINITION

Cefazolin Sodium has a potency equivalent to NLT 89.1% and NMT 110.1% of cefazolin sodium ($C_{14}H_{13}N_8NaO_4S_3$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#): 197A or 197K ▲ (CN 1-May-2020)

Solution A: Acetone and water (9:1)

Standard: [USP Cefazolin RS](#)

Sample: 150 mg

Analysis: Dissolve the *Sample* in 5 mL of [water](#), add 0.5 mL of [2 N acetic acid](#), swirl, and allow to stand for 10 min in an ice bath. Filter the precipitate, and rinse with 1–2 mL of [water](#). Dissolve in *Solution A*, evaporate the solvent almost to dryness, and dry in an oven at 60° for 30 min.

Acceptance criteria: Meets the requirements

- **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 \(191\)](#), [Chemical Identification Tests, Sodium](#): Meets the requirements

ASSAY

• PROCEDURE

Protect all solutions containing cefazolin from light.

Buffer A: 0.9 g/L of [anhydrous dibasic sodium phosphate](#) and 1.3 g/L of [citric acid](#) in water

Buffer B: 5.7 g/L of [anhydrous dibasic sodium phosphate](#) and 3.6 g/L of [monobasic potassium phosphate](#) in [water](#)

Mobile phase: [Acetonitrile](#) and *Buffer A* (1:9). Pass through a suitable filter.

Standard solution: 50 µg/mL of [USP Cefazolin RS](#) in *Buffer B*

Sample solution: 50 µg/mL of Cefazolin Sodium in *Buffer B*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cefazolin sodium ($C_{14}H_{13}N_8NaO_4S_3$) in the portion of Cefazolin Sodium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times P \times 100$$

r_U = peak response of cefazolin from the *Sample solution*

r_S = peak response of cefazolin from the *Standard solution*

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

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

M_{r1} = molecular weight of cefazolin sodium, 476.49

M_{r2} = molecular weight of cefazolin, 454.51

P = potency of [USP Cefazolin RS](#) (mg/mg)

Acceptance criteria: 89.1%–110.1% on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES

Protect all solutions containing cefazolin from light.

Solution A: 6.8 g/L of [monobasic potassium phosphate](#)

Solution B: 6.8 g/L of [monobasic potassium phosphate](#) adjusted with 10% [sodium hydroxide](#) to a pH of 6.8 before final dilution

Solution C: Acetonitrile and *Solution A* (1:1)

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

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	98	2
7	98	2
15	85	15
30	80	20
35	80	20
45	50	50
50	50	50
55	98	2
65	98	2

Blank: *Solution B*

System suitability stock solution: 2 mg/mL of [USP Cefazolin RS](#) in 0.05 M [sodium hydroxide](#). Set the solution aside at room temperature for 5 min. [NOTE—The cefazolin epimer is formed upon treatment of cefazolin with sodium hydroxide.]

System suitability solution: *System suitability stock solution* and *Solution B* (1:24)

Standard solution: 25 µg/mL of [USP Cefazolin RS](#) in *Solution B*. Use this solution promptly after preparation.

Sample solution: 2.5 mg/mL of Cefazolin Sodium in *Solution B*. Use this solution promptly after preparation.

Chromatographic system

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

Mode: LC

Detector: UV 210 and 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 30°

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability