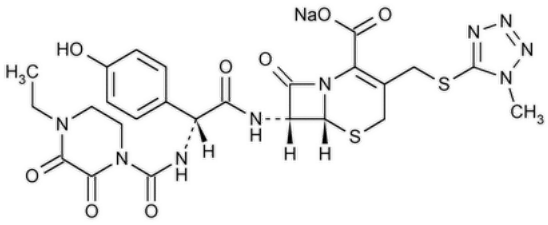
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2023
Document Type: USP Monographs
DocId: GUID-EF5F1FD5-8DD7-4ECC-ADA0-98B60F7E72B7_4_en-US
DOI: https://doi.org/10.31003/USPNF_M14039_04_01
DOI Ref: edu4w

Cefoperazone Sodium

Change to read:



$C_{25}H_{26}N_9NaO_8S_2$ 667.65

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[[(4-ethyl-2,3-dioxo-1-piperazinyl)carbonyl]amino](4-hydroxyphenyl)acetyl]amino]-3-[[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-, monosodium salt, [6*R*-[6α,7β (*R**)]]-;

Sodium (6*R*,7*R*)-7-[(*R*)-2-(4-ethyl-2,3-dioxo-1-piperazinecarboxamido)-2-(▲4▲ (USP 1-Dec-2023) -hydroxyphenyl)acetamido]-3-{[(1-methyl-▲1▲ (USP 1-Dec-2023) *H*-tetrazol-5-yl)thio]methyl}-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate CAS RN®: 62893-20-3; UNII: 5FQG9774WD.

DEFINITION

Cefoperazone Sodium contains the equivalent of NLT 870 µg/mg and NMT 1015 µg/mg of cefoperazone ($C_{25}H_{27}N_9O_8S_2$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** **Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*:** Meets the requirements

ASSAY

Change to read:

- **Procedure**

Solution A: Place 14 mL of triethylamine and 5.7 mL of glacial acetic acid in a 100-mL volumetric flask, and dilute with water to volume.

Mobile phase: Acetonitrile, ▲1 M acetic acid TS,▲ (USP 1-Dec-2023) *Solution A*, and water (120: 2.8: 1.2: 876)

Standard solution: 0.16 mg/mL of cefoperazone from USP Cefoperazone Dihydrate RS in *Mobile phase*

Sample solution: 0.16 mg/mL of cefoperazone from Cefoperazone Sodium in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: ▲3.9-mm▲ (USP 1-Dec-2023) × 30-cm; ▲10-µm▲ (USP 1-Dec-2023) 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 ▲0.73%▲ (USP 1-Dec-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefoperazone ($C_{25}H_{27}N_9O_8S_2$) in the portion of Cefoperazone Sodium taken:

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

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

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

C_S = concentration of cefoperazone in the *Standard solution* (mg/mL)

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

P = potency of cefoperazone in USP Cefoperazone Dihydrate RS (µg/mg)

Acceptance criteria: 870–1015 µg/mg on the anhydrous basis

SPECIFIC TESTS

- **Crystallinity ⟨695⟩:** Meets the requirements
- **pH ⟨791⟩**

  Sample solution: 250 mg/mL of Cefoperazone Sodium in water

  Acceptance criteria: 4.5–6.5
- **Water Determination ⟨921⟩, *Method I*:** NMT 5.0%

Delete the following:

- ▲**Sterility Tests ⟨71⟩**▲ (USP 1-Dec-2023)

Delete the following:

- ▲**Bacterial Endotoxins Test ⟨85⟩**▲ (USP 1-Dec-2023)

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.

Delete the following:

- ▲**Labeling**▲ (USP 1-Dec-2023)
- **USP Reference Standards ⟨11⟩**

  USP Cefoperazone Dihydrate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 48(3)

Current DocID: GUID-EF5F1FD5-8DD7-4ECC-ADA0-98B60F7E72B7_4_en-US

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