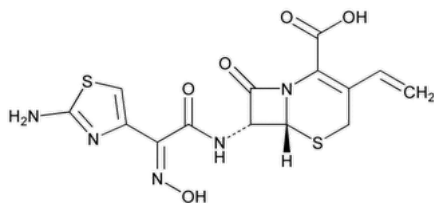


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## Cefdinir



$C_{14}H_{13}N_5O_5S_2$  395.41

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(2-amino-4-thiazolyl)(hydroxyimino)acetyl]amino]-3-ethenyl-8-oxo-, [6R-[6 $\alpha$ ,7 $\beta$ (Z)]]-; (-)-(6R,7R)-7-[2-(2-Amino-4-thiazolyl)glyoxylamido]-8-oxo-3-vinyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7<sup>2</sup>-(Z)-oxime CAS RN®: 91832-40-5; UNII: C10FAO63WC.

### DEFINITION

Cefdinir contains NLT 940 µg/mg and NMT 1030 µg/mg of cefdinir ( $C_{14}H_{13}N_5O_5S_2$ ), calculated on the anhydrous basis.

### IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#)
- **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

**Solution A:** 14.2 g/L of anhydrous dibasic sodium phosphate

**Solution B:** 13.6 g/L of monobasic potassium phosphate

**Solution C:** Dilute tetramethylammonium hydroxide (10%) with water to obtain a 0.1% solution. Adjust with 10% phosphoric acid to a pH of 5.5.

**Solution D:** 37.2 mg/mL of edetate disodium

**Buffer:** Combine appropriate amounts of *Solution A* and *Solution B* (about 2:1) to obtain a solution with a pH of 7.0.

**Mobile phase:** Acetonitrile, methanol, *Solution C*, and *Solution D* (300:200:4500:2)

**System suitability solution:** 0.2 mg/mL of [USP Cefdinir RS](#) and 0.5 mg/mL of [USP Cefdinir Related Compound A RS](#) in *Buffer*

**Standard solution:** 0.2 mg/mL of [USP Cefdinir RS](#) in *Buffer*

**Sample solution:** 0.2 mg/mL of Cefdinir in *Buffer*

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Column temperature:** 40°

**Flow rate:** 1 mL/min

**Injection size:** 5 µL

#### System suitability

**Samples:** *System suitability solution* and *Standard solution*. [USP Cefdinir Related Compound A RS](#) should produce four peaks.

**Tailing factor:** NMT 1.5 for cefdinir, *System suitability solution*

**Resolution:** NLT 1.2 between the second peak of cefdinir related compound A and cefdinir, *System suitability solution*

**Relative standard deviation:** NMT 1.0%, *Standard solution*

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefdinir ( $C_{14}H_{13}N_5O_5S_2$ ) in the portion of Cefdinir 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 the *Standard solution* (mg/mL)

$C_u$  = concentration of the *Sample solution* (mg/mL)

$P$  = purity of [USP Cefdinir RS](#) (µg/mg)

**Acceptance criteria:** 940–1030 µg/mg on the anhydrous basis

#### IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.20%

**Change to read:**

- **ORGANIC IMPURITIES**

**Solution A, Solution B, Solution C, Solution D, and Buffer:** Prepare as directed in the Assay.

**Solution E:** To 1000 mL of *Solution C* add 0.4 mL of *Solution D*.

**Solution F:** Acetonitrile, methanol, *Solution C*, and *Solution D* (300:200:500:0.4)

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

**Table 1**

| Time<br>(min) | Solution E<br>(%) | Solution F<br>(%) |
|---------------|-------------------|-------------------|
| 0             | 95                | 5                 |
| 2             | 95                | 5                 |
| 22            | 75                | 25                |
| 32            | 50                | 50                |
| 37            | 50                | 50                |
| 38            | 95                | 5                 |
| 58            | 95                | 5                 |

**System suitability solution 1:** 15 µg/mL of cefdinir from the *Sample solution*, diluted with *Solution C*

**System suitability solution 2:** 1.5 µg/mL of cefdinir from *System suitability solution 1*, diluted with *Solution C*

**System suitability solution 3:** 1.5 mg/mL of [USP Cefdinir RS](#) and 0.1 mg/mL of [USP Cefdinir Related Compound A RS](#), dissolved initially in *Buffer* corresponding to 15% of the final volume, and diluted with *Solution C* to volume

**Sample stock solution:** 10 mg/mL of Cefdinir in *Buffer*

**Sample solution:** 1.5 mg/mL of cefdinir from the *Sample stock solution*, in *Solution C*. [NOTE—Prepare fresh immediately before use.]

#### Chromatographic system

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

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 15-cm; 5-µm packing L1

**Column temperature:** 40°

**Flow rate:** 1 mL/min

**Injection size:** 10 µL

#### System suitability

**Samples:** *System suitability solution 1*, *System suitability solution 2*, and *System suitability solution 3*. [USP Cefdinir Related Compound A RS](#) should produce four peaks.

#### Suitability requirements

**Response ratio:** The response of cefdinir from *System suitability solution 2* is between 7% and 13% of that from *System suitability solution 1*.

**Resolution:** NLT 1.5 between cefdinir and the third peak of [USP Cefdinir Related Compound A RS](#), *System suitability solution 3*

**Relative standard deviation:** NMT 2.0% for cefdinir, *System suitability solution 3*

#### Analysis

**Sample:** *Sample solution*. Record the chromatogram for at least 1.8 times the retention time of the cefdinir peak.

Calculate the percentage of each impurity in the portion of Cefdinir taken:

$$\text{Result} = (r_u/r_r) \times 100$$