

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Dec-2023
 Document Type: USP Monographs
 DocId: GUID-ED8E5319-F91E-494D-A823-8DB438663ED7_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M2183_03_01
 DOI Ref: 86bn4

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Cefdinir Capsules

DEFINITION

Cefdinir Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of cefdinir ($C_{14}H_{13}N_5O_5S_2$).

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#)

Buffer: Prepare as directed in the Assay.

Standard solution: 10 µg/mL of [USP Cefdinir RS](#) in *Buffer*

Sample solution: Equivalent to 10 µg/mL of cefdinir from Capsules in *Buffer*. Filter before use.

Cell size: 1 cm

Blank: Use the *Buffer*.

Acceptance criteria: *Sample solution* maxima and minima occur at the same wavelengths as those in the *Standard solution*.

- **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

Buffer: 10.7 g/L of dibasic sodium phosphate and 3.4 g/L of monobasic potassium phosphate. Adjust with phosphoric acid or sodium hydroxide to a pH of 7.0 ± 0.05 before final dilution.

Solution A: 7 g/L of citric acid monohydrate. Adjust with phosphoric acid to a pH of 2.0 ± 0.05 .

Mobile phase: Methanol, tetrahydrofuran, and *Solution A* (111:28:1000)

System suitability solution: 50 µg/mL of [USP Cefdinir RS](#) and 175 µg/mL of *m*-hydroxybenzoic acid in *Buffer*

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

Sample solution: Equivalent to 50 µg/mL of cefdinir, from Capsule contents (NLT 20), in *Buffer*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 15-cm; 4-µm packing L1

Flow rate: 1.4 mL/min

Injection volume: 15 µL

System suitability

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

Suitability requirements

Resolution: Greater than 3.0 between cefdinir and *m*-hydroxybenzoic acid, *System suitability solution*

Tailing factor: NMT 2.0 for cefdinir, *System suitability solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefdinir ($C_{14}H_{13}N_5O_5S_2$) in the portion of Capsules taken:

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

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

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

C_S = concentration of the *Standard solution* (µg/mL)

C_U = nominal concentration of cefdinir in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [DISSOLUTION \(711\)](#)

Medium: 50 mM phosphate buffer, pH 6.8; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Detector: UV 290 nm

Cell length: 0.1-cm flow cell

Standard solution: 0.33 mg/mL of [USP Cefdinir RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size. Dilute with *Medium* to a concentration of about 0.33 mg/mL of cefdinir.

Blank: Dissolve 1 empty Capsule in 100 mL of *Medium*, and dilute to 900 mL. Filter if necessary.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefdinir ($C_{14}H_{13}N_5O_5S_2$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution* (mL/mL)

L = label claim (mg/Capsule)

Tolerances: NLT 80% (Q) of the labeled amount of cefdinir ($C_{14}H_{13}N_5O_5S_2$) is dissolved.

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

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

Solution B: 13.6 g/L of monobasic potassium phosphate

Buffer: Combine appropriate amounts of *Solution A* and *Solution B* (about 2:1) to obtain a solution with a pH of 7.0 ± 0.1 .

Solution C: Dilute tetramethylammonium hydroxide (10% aqueous) with water to obtain a 0.1% solution. Adjust with dilute phosphoric acid (1 in 10) to a pH of 5.5 ± 0.1 .

Solution D: 37.2 mg/mL of edetate disodium

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

Solution F: Acetonitrile, methanol, *Solution C*, and *Solution D* (150:100:250:0.2)

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

Table 1

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

System suitability stock solution 1: 40 µg/mL of [USP Cefdinir Related Compound A RS](#) in *Solution C*

System suitability stock solution 2: 40 µg/mL of [USP Cefdinir Related Compound B RS](#) in *Solution C*

System suitability solution: Transfer 37.5 mg of [USP Cefdinir RS](#) to a 25-mL volumetric flask. Add about 10 mL of *Buffer*. Add 5.0 mL each of *System suitability stock solution 1* and *System suitability stock solution 2*, and dilute with *Solution C* to volume.

Standard stock solution: 750 µg/mL of [USP Cefdinir RS](#) in *Buffer*