

Status: Currently Official on 14-Feb-2025
 Official Date: Official as of 01-Dec-2023
 Document Type: USP Monographs
 DocId: GUID-5D770B74-15B2-458B-98C8-64F91A49572C_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M2184_03_01
 DOI Ref: ob9q2

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Cefdinir for Oral Suspension

DEFINITION

Cefdinir for Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of cefdinir ($C_{14}H_{13}N_5O_5S_2$). It may contain one or more suitable buffers, flavors, preservatives, stabilizing agents, sweeteners, and suspending agents.

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.** The UV spectrum of the cefdinir 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 [sodium phosphate, dibasic, anhydrous](#) and 3.4 g/L of [potassium phosphate, monobasic](#) in [water](#). Adjust with [phosphoric acid](#) or [sodium hydroxide](#) to a pH of 7.0.

Solution A: 7 g/L of citric acid monohydrate. Adjust with [phosphoric acid](#) to a pH of 2.0.

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: Nominally 50 µg/mL of cefdinir from constituted Cefdinir for Oral Suspension in *Buffer*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 3.9-mm × 15-cm; 4-µm packing [L1](#)

Flow rate: 1.4 mL/min

Injection volume: 15 µL

Run time: NLT 3 times the retention time of cefdinir

System suitability

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

Suitability requirements

Resolution: NLT 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 Cefdinir for Oral Suspension 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 [USP Cefdinir RS](#) in 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: 0.05 M phosphate buffer, pH 6.8; 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 0.14 mg/mL of [USP Cefdinir RS](#) in *Medium*

Sample solution: Transfer 5 mL, by weight, of the reconstituted Cefdinir for Oral Suspension into the vessel. After the appropriate time, withdraw a portion of the solution under test, and pass it through a suitable filter of 0.45-µm pore size. Dilute a portion of each filtered sample with *Medium* as necessary to obtain a solution with a concentration of about 0.14 mg/mL of cefdinir.

Instrumental conditions

Mode: UV

Analytical wavelength: 290 nm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

A_U = absorbance from the *Sample solution*

A_S = absorbance from the *Standard solution*

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

d = density of Cefdinir for Oral Suspension (mg/mL)

W = weight of reconstituted Cefdinir for Oral Suspension taken (mg)

V = volume of *Medium*, 900 mL

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

L = label claim (mg/mL)

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

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#)

For single-unit containers: Meets the requirements

• [DELIVERABLE VOLUME \(698\)](#)

For multiple-unit containers: Meets the requirements

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 14.2 g/L of [sodium phosphate, dibasic, anhydrous](#)

Solution B: 13.6 g/L of [potassium phosphate, monobasic](#)

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

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

Solution D: 37.2 g/L 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*



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