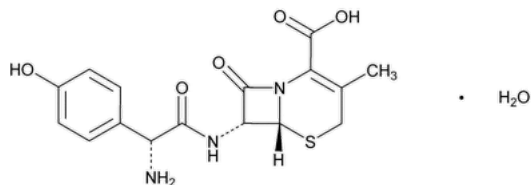


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Cefadroxil



$C_{16}H_{17}N_3O_5S \cdot H_2O$ 381.40

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[amino(4-hydroxyphenyl)acetyl]amino]-3-methyl-8-oxo-, monohydrate, [6*R*-[6*α*,7*β* (*R*^{*})]]; (6*R*,7*R*)-7-[(*R*)-2-Amino-2-(*p*-hydroxyphenyl)acetamido]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid monohydrate CAS RN[®]: 66592-87-8; UNII: 280111G160.

Hemihydrate 372.40 CAS RN[®]: 119922-85-9; UNII: J9CMF6461M.

Anhydrous 363.39 CAS RN[®]: 50370-12-2; UNII: Q525PA8JJB.

DEFINITION

Cefadroxil has a potency equivalent to NLT 950 µg/mg and NMT 1050 µg/mg of cefadroxil ($C_{16}H_{17}N_3O_5S$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)▲ (CN 1-MAY-2020)
- **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: 2.7 g/L of monobasic potassium phosphate

Mobile phase: Acetonitrile and *Buffer* (4:96)

Standard solution: 50 µg/mL of [USP Cefadroxil RS](#) in *Mobile phase* prepared as follows. Transfer a suitable quantity of [USP Cefadroxil RS](#) to a suitable volumetric flask, dissolve in *Mobile phase* using 50% of the final volume, sonicate to dissolve, and dilute with *Mobile phase* to volume.

Sample solution: 50 µg/mL of Cefadroxil in *Mobile phase* prepared as follows. Transfer a suitable quantity of Cefadroxil to a suitable volumetric flask, dissolve in *Mobile phase* using 50% of the final volume, sonicate to dissolve, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity, in µg/mg, of cefadroxil ($C_{16}H_{17}N_3O_5S$) in the portion of Cefadroxil 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 [USP Cefadroxil RS](#) in the *Standard solution* (µg/mL)

C_u = concentration of Cefadroxil in the *Sample solution* (µg/mL)

P = potency of cefadroxil in [USP Cefadroxil RS](#) (µg/mg)

Acceptance criteria: 950–1050 µg/mg on the anhydrous basis

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 50 mg/mL of sodium hydroxide

Solution B: 4 g/L of monobasic sodium phosphate dihydrate adjusted with *Solution A* to a pH of 5.0

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

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

Table 1

Time (min)	Solution B (%)	Solution C (%)
0	100	0
35	85	15
50	40	60
60	0	100
61	100	0
70	100	0

Diluent: 3.5 g/L of monobasic potassium phosphate and 4.6 g/L of dibasic sodium phosphate anhydrous

System suitability stock solution 1: 0.5 mg/mL of [USP Cefadroxil Related Compound D RS](#) in *Diluent*. Sonicate as needed to dissolve.

System suitability stock solution 2: 0.5 mg/mL of [USP Cefadroxil Related Compound I RS](#) in *Diluent*. Sonicate as needed to dissolve.

System suitability solution: 10 µg/mL of cefadroxil related compound D from *System suitability stock solution 1*, 10 µg/mL of cefadroxil related compound I from *System suitability stock solution 2*, and 1 mg/mL of [USP Cefadroxil System Suitability Mixture RS](#) in *Solution B*. Store the sample in the refrigerator, and discard after 14 h.

Standard solution: 10 µg/mL of [USP Cefadroxil RS](#) in *Solution B*. Store the sample in the refrigerator, and discard after 14 h.

Sample solution: 1 mg/mL of Cefadroxil in *Solution B*. Store the sample in the refrigerator, and discard after 14 h.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Autosampler temperature: 6°

Injection volume: 20 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between cefadroxil related compound D and cefadroxil related compound I, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times P \times F \times 100$$

r_u = peak response of each impurity from the *Sample solution*

r_s = peak response of cefadroxil from the *Standard solution*

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