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Cefadroxil Capsules

DEFINITION

Cefadroxil Capsules contain the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of cefadroxil ($C_{16}H_{17}N_3O_5S$).

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.

ASSAY

• PROCEDURE

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Adjust with 10 N potassium hydroxide to a pH of 5.0.

Mobile phase: Acetonitrile and *Buffer* (40:960)

Standard solution: 1.06 mg/mL of [USP Cefadroxil RS](#) in *Buffer*. This solution contains the equivalent of 1 mg/mL of cefadroxil. Use this solution on the day prepared.

Sample solution: Remove the contents of NLT 10 Capsules as completely as possible, and weigh. Transfer a portion of the powder, nominally equivalent to 200 mg of cefadroxil, to a 200-mL volumetric flask. Dilute with *Buffer* to volume, and stir by mechanical means for 5 min. Use this solution on the day prepared.

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

Column: 4-mm × 25-cm; 5-μm packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.2

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefadroxil ($C_{16}H_{17}N_3O_5S$) in the portion of Capsules taken:

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

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* (mg/mL)

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

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

F = conversion factor, 0.001 mg/μg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Standard solution: [USP Cefadroxil RS](#) in *Medium* at a known concentration similar to that in the *Sample solution*

Sample solution: Sample per [Dissolution \(711\)](#). Suitably dilute with *Medium*, if necessary, and filter.

Analysis: Determine the amount of cefadroxil ($C_{16}H_{17}N_3O_5S$) dissolved from UV absorbances at 263 nm of the *Sample solution* in comparison to the *Standard solution*.

Tolerances: NLT 80% (*Q*) of the labeled amount of cefadroxil ($C_{16}H_{17}N_3O_5S$) is dissolved.

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

IMPURITIES

• ORGANIC IMPURITIES

Solution A: 50 mg/mL of sodium hydroxide

Solution B: 4 g/L of monobasic sodium phosphate dihydrate in water, adjusted with *Solution A* to a pH of 5.2

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 refrigerated, and discard after 14 h.

Standard solution: 10 µg/mL of [USP Cefadroxil RS](#) in *Solution B*

Sample solution: Nominally, 1 mg/mL of cefadroxil in *Solution B* prepared as follows. Transfer the finely powdered contents of NLT 10 Capsules to a suitable volumetric flask, and add 50% of the final volume of *Solution B*. Sonicate with intermittent shaking. Cool to room temperature, dilute with *Solution B* to final volume, and mix. Centrifuge a portion of this solution, and filter the supernatant solution. Store refrigerated, 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

Injection volume: 20 µL

Autosampler temperature: 6°

System suitability

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

[NOTE—The relative retention times for cefadroxil related compound D, cefadroxil related compound I, and cefadroxil are about 0.71, 0.80, and 1.0, respectively.]

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 Capsules taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times (F_1/F_2) \times 100$$

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