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Cefadroxil Tablets

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

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Standard solution: 2 mg/mL of USP Cefadroxil RS

Sample solution: Nominally 2 mg/mL of cefadroxil from powdered Tablets dissolved in water and filtered

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Adsorbent: 0.25-mm layer of binder-free silica gel

Application volume: 20 µL

Pre-developing solvent solution: *n*-Hexane and tetradecane (95:5)

Solution A: 66.7-mg/mL solution of ninhydrin in acetone

Developing solvent system: 0.1 M citric acid, 0.1 M dibasic sodium phosphate, and *Solution A* (60:40:1.5)

Spray reagent: 2-mg/mL solution of ninhydrin in dehydrated alcohol. Protect from light.

Analysis

Samples: *Standard solution* and *Sample solution*

Place the thin-layer chromatographic plate in a chamber containing the *Pre-developing solvent solution* to a depth of about 1 cm, and allow the solvent front to move the length of the plate. Remove the plate from the chamber, and allow the solvent to evaporate. Apply the *Sample solution* and *Standard solution* to the plate, allow the spots to dry, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow to air-dry. Spray the plate with the *Spray reagent*, dry for 10 min at 110°, and examine the chromatogram.

Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate in water, adjusted 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 nominally 1 mg/mL of cefadroxil. Use this solution on the day prepared.

Sample solution: Nominally 1 mg/mL of cefadroxil from finely powdered Tablets (NLT 10) in *Buffer*. 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; packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Capacity factor, k': 2.0–3.5

Column efficiency: NLT 1800 theoretical plates

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 Tablets 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 2: 50 rpm

Time: 30 min

Standard solution: Prepare a solution having a known concentration of USP Cefadroxil RS in *Medium*.

Sample solution: Sample per ⟨711⟩. Pass a portion of the solution under test through a suitable filter, and dilute with water if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: 263 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: NLT 75% (*Q*) of the labeled amount of cefadroxil ($C_{16}H_{17}N_3O_5S$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

SPECIFIC TESTS

• **Water Determination,** *Method I*⟨921⟩**:** NMT 8.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** The Tablets prepared using the hemihydrate form of cefadroxil are so labeled.

• **USP Reference Standards** ⟨11⟩

USP Cefadroxil RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CEFADROXIL TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

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