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Cefadroxil for Oral Suspension

DEFINITION

Cefadroxil for Oral Suspension is a dry mixture of Cefadroxil and one or more suitable buffers, colors, diluents, and flavors. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of $C_{16}H_{17}N_3O_5S$.

IDENTIFICATION

• **Thin-Layer Chromatography**

Standard solution: 2 mg/mL of USP Cefadroxil RS

Sample solution: Constitute 1 container of Cefadroxil for Oral Suspension as directed in the labeling. Dilute a portion of the resulting suspension with water to a concentration of 2 mg/mL. Pass through a suitable filter.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

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

Application volume: 20 µL

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

Solution A: 1 in 15 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: 1 in 500 solution of ninhydrin in dehydrated alcohol. Protect this solution from light.

Analysis

Samples: *Standard solution* and *Sample solution*

Place the thin-layer chromatographic plate in a chamber containing the *Pre-developing solvent system* 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: 6.86 g/L of monobasic potassium phosphate. 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*. Use this solution on the day prepared. [Note—This solution contains the equivalent of 1 mg/mL of cefadroxil ($C_{16}H_{17}N_3O_5S$).]

Sample solution: Constitute a container of Cefadroxil for Oral Suspension as directed in the labeling. Dilute a portion of the resulting suspension with *Buffer* to prepare a solution containing nominally 1 mg/mL. Pass through a suitable filter of 0.8-µm or finer pore size, and use the filtrate. 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 size: 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 Cefadroxil for Oral Suspension taken:

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

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

r_S = peak response of cefadroxil 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: 25 rpm

Time: 30 min

Standard solution: USP Cefadroxil RS in *Medium* at a known concentration

Sample solution: Transfer 5.0 mL of the constituted Cefadroxil for Oral Suspension (weighed) to the dissolution vessel.

Analysis: Determine the amount of cefadroxil dissolved by employing UV absorption at the wavelength of 263 nm on the *Sample solution* in comparison with the *Standard solution*.

Calculate the amount of cefadroxil dissolved:

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

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

Tolerances: NLT 75% (Q) of the labeled amount of cefadroxil is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩

For solid packaged in single-unit containers: Meets the requirements

• **Deliverable Volume** ⟨698⟩**:** Meets the requirements

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.5–6.0, in the suspension constituted as directed in the labeling

• **Water Determination,** *Method I* ⟨921⟩**:** NMT 2.0%, except where it is labeled as containing 100 mg of cefadroxil per mL after constitution, in which case the limit is NMT 3.0%

ADDITIONAL REQUIREMENTS

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

• **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 FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(6)
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