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Cefprozil for Oral Suspension

DEFINITION

Cefprozil for Oral Suspension is a dry mixture of Cefprozil and one or more suitable buffers, flavors, preservatives, suspending agents, and sweeteners. It contains NLT 90.0% and NMT 120.0% of the labeled amount of cefprozil ($C_{18}H_{19}N_3O_5S$).

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Diluent: Acetone and 0.1 N hydrochloric acid (4:1)

Standard solution: 5 mg/mL of USP Cefprozil (*Z*)-Isomer RS in *Diluent*

Sample solution: Nominally 5 mg/mL of cefprozil in *Diluent* from Cefprozil for Oral Suspension. Shake for 5 min, and allow to settle. Use the supernatant.

Chromatographic system

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

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Butyl alcohol, glacial acetic acid, and water (60:20:20)

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the spots to dry, and develop the chromatogram in an equilibrated chamber with the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate, and allow it to air-dry in a hood. Place the dry plate in a chamber containing iodine vapors. Examine the plate, and locate the spots.

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

• **B.** The retention times of the cefprozil (*Z*)-isomer and cefprozil (*E*)-isomer peaks of the *Sample solution* correspond to those of *Standard solution 1* and *Standard solution 2*, respectively, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 11.5 g/L of monobasic ammonium phosphate in water. Adjust, if necessary, with phosphoric acid to a pH of 4.4.

Mobile phase: Acetonitrile and *Buffer* (100:900). [Note—Decreasing the proportion of acetonitrile increases retention times and improves the resolution between the cefprozil isomer peaks.]

Standard solution 1: 0.25 mg/mL of USP Cefprozil (*Z*)-Isomer RS. Use this solution within 6 h.

Standard stock solution: 0.25 mg/mL of USP Cefprozil (*E*)-Isomer RS

Standard solution 2: 0.025 mg/mL of USP Cefprozil (*E*)-Isomer RS in water from the *Standard stock solution*. Use this solution within 6 h.

System suitability solution: A mixture of equal volumes of *Standard solution 1* and the *Standard stock solution*. Use this solution within 6 h.

Sample stock solution: Nominally 1 mg/mL of cefprozil in water from Cefprozil for Oral Suspension. Prepare as follows. Constitute one container of Cefprozil for Oral Suspension as directed in the labeling. Transfer a suitable aliquot, freshly mixed and free from air bubbles, to a volumetric flask, dilute with water to volume, and mix, sonicating briefly.

Sample solution: Nominally 0.3 mg/mL of cefprozil in water from the *Sample stock solution*. Pass a portion of this solution through a filter of 0.5-µm or finer pore size. Use this solution within 6 h.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution 1* and *System suitability solution*

[Note—The relative retention times for the cefprozil (*Z*)-isomer and the cefprozil (*E*)-isomer are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.5 between cefprozil (*Z*)-isomer and cefprozil (*E*)-isomer, *System suitability solution*

Column efficiency: NLT 2500 theoretical plates, cefprozil (*Z*)-isomer, *Standard solution 1*

Calculate as follows:

$$\text{Result} = (t_R/W_{h/2})^2 \times 5.545$$

t_R = retention time of cefprozil (*Z*)-isomer

$W_{h/2}$ = peak width at half-height

Tailing factor: 0.9–1.1, cefprozil (*Z*)-isomer, *Standard solution 1*

Calculate as follows:

$$\text{Result} = W_{0.1}/2f$$

$W_{0.1}$ = width of the peak at 10% height

f = distance from the peak maximum to the leading edge of the peak measured at 10% of the peak height

Relative standard deviation: NMT 2.0%, *Standard solution 1*

Analysis

Samples: *Standard solution 1*, *Standard solution 2*, and *Sample solution*

Calculate the concentration, in mg/mL, of the cefprozil (*Z*)-isomer in the *Sample solution*:

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

r_U = peak response of the cefprozil (*Z*)-isomer from the *Sample solution*

r_S = peak response of the cefprozil (*Z*)-isomer from *Standard solution 1*

C_S = concentration of USP Cefprozil (*Z*)-Isomer RS in *Standard solution 1* (mg/mL)

P = potency of the cefprozil (*Z*)-isomer in USP Cefprozil (*Z*)-Isomer RS (µg/mg)

F = correction factor, 0.001 mg/µg

Calculate the concentration, in mg/mL, of the cefprozil (*E*)-isomer in the *Sample solution*:

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

r_U = peak response of the cefprozil (*E*)-isomer from the *Sample solution*

r_S = peak response of the cefprozil (*E*)-isomer from *Standard solution 2*

C_S = concentration of USP Cefprozil (*E*)-Isomer RS in *Standard solution 2* (mg/mL)

P = potency of the cefprozil (*E*)-isomer in USP Cefprozil (*E*)-Isomer RS (µg/mg)

F = correction factor, 0.001 mg/µg

Calculate the percentage of the labeled amount of cefprozil ($C_{18}H_{19}N_3O_5S$) in the portion of Cefprozil for Oral Suspension taken:

$$\text{Result} = [(C_Z + C_E)/C_U] \times 100$$

C_Z = concentration of the cefprozil (*Z*)-isomer in the *Sample solution* (mg/mL)

C_E = concentration of the cefprozil (*E*)-isomer in the *Sample solution* (mg/mL)

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

Acceptance criteria: 90%–120.0%

PERFORMANCE TESTS

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

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

- **Deliverable Volume ⟨698⟩**

For solids packaged in multiple-unit containers: Meets the requirements

SPECIFIC TESTS

- **pH ⟨791⟩**

Sample solution: Constitute Cefprozil for Oral Suspension as directed in the labeling.

Acceptance criteria: 4.0–6.0

• **Water Determination, *Method I*⟨921⟩:** NMT 3.0%

ADDITIONAL REQUIREMENTS

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

• **USP Reference Standards ⟨11⟩**

USP Cefprozil (*E*)-Isomer RS

USP Cefprozil (*Z*)-Isomer RS

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

Topic/Question	Contact	Expert Committee
CEFPROZIL FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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