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Cefuroxime Axetil for Oral Suspension

DEFINITION
Cefuroxime Axetil for Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of cefuroxime ($C_{16}H_{16}N_4O_8S$).

IDENTIFICATION
The retention times of the major peaks for cefuroxime axetil diastereoisomers A and B of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY
Change to read:

• **Procedure**

Solution A: 23 g/L of monobasic ammonium phosphate in water

Mobile phase: Methanol and *Solution A* (19:31)

System suitability stock solution A: 1.2 mg/mL of USP Cefuroxime Axetil RS in methanol

System suitability stock solution B: 0.16 mg/mL of USP Cefuroxime Axetil Delta-3-Isomers RS in methanol

System suitability solution: Transfer 10.0 mL of *System suitability stock solution A* to a 50-mL volumetric flask. Add 5.0 mL of methanol and 3.8 mL of *System suitability stock solution B*. Dilute with *Solution A* to volume.

Standard stock solution: 1.2 mg/mL of USP Cefuroxime Axetil RS in methanol. [Note—Use this solution promptly.]

Standard solution: Transfer 10.0 mL of *Standard stock solution* to a 50-mL volumetric flask, add 8.8 mL of methanol, and dilute with *Solution A* to volume. [Note—Use this *Standard solution* promptly, or refrigerate and use on the day prepared.]

Sample stock solution: Equivalent to 2.5 mg/mL of cefuroxime, from constituted Oral Suspension, in methanol. Pass through a suitable filter. [Note—Constitute as directed on the label. To a suitable aliquot, freshly prepared and free of bubbles, add a suitable volume of methanol, shake by mechanical means for 10 min, dilute to volume with methanol, and mix.]

Sample solution: Transfer 5.0 mL of the filtered *Sample stock solution* to a 50-mL volumetric flask. Add 13.8 mL of methanol, and dilute with *Solution A* to volume. [Note—Protect the *Sample solution* from light and use promptly, or refrigerate and use on the day prepared.]

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

Mode: LC

Detector: UV 278 nm

Column: 4.6-mm × 25-cm; 5-µm packing L13

Flow rate: 1.5 mL/min

Injection size: 10 µL

System suitability

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

[Note—The relative retention times for ▲cefuroxime axetil diastereoisomer B, cefuroxime axetil diastereoisomer A, and cefuroxime axetil delta-3 isomers are 0.8, 0.9, and 1.0,▲ (ERR 1-Jun-2024) respectively.]

Suitability requirements

Resolution: NLT 1.5 between cefuroxime axetil diastereoisomer A and B; NLT 1.5 between cefuroxime axetil diastereoisomer A and cefuroxime axetil delta-3 isomers, *System suitability solution*

Column efficiency: NLT 3000 theoretical plates when measured using the cefuroxime axetil diastereoisomer A peak, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{16}H_{16}N_4O_8S$ in the Cefuroxime Axetil for Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times P \times F \times [1 - (K/100)] \times 100$$

R_U = sum of the peak responses of cefuroxime axetil diastereoisomers A and B from the *Sample solution*

R_S = sum of the peak responses of cefuroxime axetil diastereoisomers A and B from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

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

P = potency of cefuroxime in anhydrous USP Cefuroxime Axetil RS (µg/mg)

F = unit conversion factor, 0.001 mg/µg

K = water content of USP Cefuroxime Axetil RS (%)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: 0.07 M of pH 7.0 phosphate buffer (dissolve 3.7 mg/mL of monobasic sodium phosphate and 5.7 mg/mL of anhydrous dibasic sodium phosphate in water); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Analysis: Test 5.0 mL of constituted Cefuroxime Axetil for Oral Suspension equivalent to 125 or 250 mg of cefuroxime. Determine the amount of cefuroxime equivalent dissolved by using UV absorption at the wavelength of maximum absorbance at 280 nm on filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a *Standard solution* having a known concentration of USP Cefuroxime Axetil RS in the same *Medium*.

Tolerances: NLT 60% (Q) of the labeled amount of $C_{16}H_{16}N_4O_8S$ is dissolved.

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

For solid packaged in single-unit containers: Constitute Cefuroxime Axetil for Oral Suspension as directed in the labeling. Mix, and allow the container to drain into a beaker for 5 s. Withdraw and assay 5.0 mL of the Oral Suspension from the beaker, or the total amount if it is less than 5 mL.

• **Deliverable Volume ⟨698⟩**

For solid packaged in multiple-unit containers: Constitute Cefuroxime Axetil for Oral Suspension as directed in the labeling. It meets the requirements.

SPECIFIC TESTS

• **pH ⟨791⟩:** 3.5–7.0, in the solution constituted as directed in the labeling

• **Water Determination, *Method I* ⟨921⟩:** NMT 6.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Cefuroxime Axetil RS

USP Cefuroxime Axetil Delta-3-Isomers RS

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

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

Chromatographic Database Information: Chromatographic Database

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