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Cefixime for Oral Suspension

DEFINITION

Cefixime for Oral Suspension is a dry mixture of Cefixime and one or more suitable diluents, flavors, preservatives, and suspending agents. It contains the equivalent of NLT 90.0% and NMT 120.0% of the labeled amount of cefixime ($C_{16}H_{15}N_5O_7S_2$)/mL when constituted as directed in the labeling.

IDENTIFICATION

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**

Solution A: 0.4 M tetrabutylammonium hydroxide solution and water (1:39). Adjust with 1.5 M phosphoric acid to a pH of 6.5.

Solution B: 13.6 mg/mL of monobasic potassium phosphate

Solution C: 14.2 mg/mL of anhydrous dibasic sodium phosphate. Adjust a volume of this solution with a sufficient volume of *Solution B* to a pH of 7.0.

Mobile phase: Acetonitrile and *Solution A* (1:3)

System suitability solution: 1 mg/mL of USP Cefixime RS. [Note—Heat this solution at 95° in an oil bath for 45 min, cool, and use promptly.]

Standard solution: 0.2 mg/mL of USP Cefixime RS in *Solution C*. [Note—Use this solution promptly.]

Sample solution: Constitute Cefixime for Oral Suspension as directed in the labeling. Quantitatively dilute a suitable aliquot of the suspension, freshly mixed and free from air bubbles, with *Solution C* to obtain a solution having a nominal concentration of 0.2 mg of cefixime/mL.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 12.5-cm; 4-µm packing L1

Temperature: 40°

Flow rate: Adjust flow rate so that the retention time of cefexime is about 10 min.

Injection size: 10 µL

System suitability

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

[Note—The relative retention times for cefixime (*E*)-isomer and cefixime are about 0.9 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between cefixime and cefixime (*E*)-isomer, *System suitability solution*

Column efficiency: NLT 4000 theoretical plates, *Standard solution*. Use the following formula to calculate column efficiency:

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

Tailing factor: NLT 0.9 and NMT 2.0 for the analyte peak, *Standard solution*. Use the following formula to calculate tailing factor:

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

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

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{16}H_{15}N_5O_7S_2$ in the constituted suspension prepared from the Cefixime for Oral Suspension:

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

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

r_S = peak response of cefixime from the *Standard solution*

C_S = concentration of USP Cefixime RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

- **Uniformity of Dosage Units ⟨905⟩ for solids packaged in single-unit containers:** Meets the requirements
- **Deliverable Volume ⟨698⟩:** Meets the requirements

SPECIFIC TESTS

- **pH ⟨791⟩:** 2.5–4.5, in the suspension constituted as directed in the labeling

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** Label it to indicate that the cefixime contained therein is in the trihydrate form.
- **USP Reference Standards ⟨11⟩**
  USP Cefixime RS

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

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

Chromatographic Database Information: Chromatographic Database

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