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Cefixime Tablets

DEFINITION
Cefixime Tablets contain the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of cefixime ($C_{16}H_{15}N_5O_7S_2$).

IDENTIFICATION
• **A.** 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: 25 mL of 0.4 M tetrabutylammonium hydroxide solution diluted with water to 1000 mL, and adjusted with 1.5 M phosphoric acid to a pH of 6.5

Solution B: 13.6 g/L of monobasic potassium phosphate in water

Solution C: 14.2 g/L of anhydrous dibasic sodium phosphate in water

Buffer: Adjust an aliquot of *Solution C* with *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 in water. 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 *Buffer*. Use this solution promptly.

Sample stock solution: Nominally 4 mg/mL of cefixime in *Buffer* from finely powdered Tablets (NLT 20). Sonicate as required, and centrifuge.

Sample solution: Nominally 0.2 mg/mL of cefixime from *Sample stock solution* in *Buffer*

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

Mode: LC

Detector: UV 254 nm

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

Column temperature: 40°

Flow rate: Adjusted so that the retention time of cefixime is about 10 min

Injection volume: 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 for the *Standard solution*

Calculate as follows:

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

t = retention time

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

Tailing factor: NLT 0.9 and NMT 2.0 for the analyte peak

Calculate as follows:

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

$W_{0.1}$ = width of peak of 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*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefixime ($C_{16}H_{15}N_5O_7S_2$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response 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)

P = potency of cefixime in USP Cefixime RS (mg/mg)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution** ⟨711⟩

Medium: 6.8 g/L of monobasic potassium phosphate in water, adjusted with 1 N sodium hydroxide to a pH of 7.2; 900 mL

Apparatus 1: 100 rpm

Time: 45 min

Detector: UV 288 nm

Standard solution: USP Cefixime RS in *Medium*. An amount of methanol not to exceed 0.1% of the total volume of the *Standard solution* may be used to bring the USP Cefixime RS into solution before dilution with *Medium*, and the solution may be sonicated to ensure complete dissolution of the USP Cefixime RS.

Sample solution: Sample per *Dissolution* ⟨711⟩. Dilute with *Medium* to a concentration similar to that of the *Standard solution*.

Tolerances: NLT 75% (*Q*)

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

SPECIFIC TESTS

• **Water Determination,** *Method I*⟨921⟩**:** NMT 10.0%

ADDITIONAL REQUIREMENTS

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

• **Labeling:** Label the Tablets 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 TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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