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Cefaclor Extended-Release Tablets

DEFINITION

Cefaclor Extended-Release Tablets contain the equivalent of NLT 90.0% and NMT 110.0% of the labeled amount of cefaclor ($C_{15}H_{14}ClN_3O_4S$).

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*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Mobile phase: Dissolve 1 g of sodium 1-pentanesulfonate in a mixture of 780 mL of water and 10 mL of triethylamine. Adjust with phosphoric acid to a pH of 2.5 ± 0.1, and add 220 mL of methanol.

System suitability solution: 0.3 mg/mL of USP Cefaclor RS and 0.3 mg/mL of USP Cefaclor Delta-3 Isomer RS in *Mobile phase*

Standard solution: 0.3 mg/mL of USP Cefaclor RS in *Mobile phase*. Sonicate briefly, if necessary, to achieve dissolution, and avoid heating the solution. Use within 8 h if stored at room temperature, or within 20 h if stored at 5°.

Sample solution: Transfer a quantity of finely powdered Tablets (NLT 20), nominally equivalent to 75 mg of cefaclor, to a 250-mL volumetric flask, and dilute with *Mobile phase* to volume. Sonicate, if necessary, to dissolve. Filter to obtain a clear solution.

Chromatographic system

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

Mode: LC

Detector: UV 265 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for cefaclor and cefaclor delta-3 isomer are about 1.0 and 1.35, respectively.]

Suitability requirements

Resolution: NLT 2.5 between the cefaclor peak and the cefaclor delta-3 isomer peak

Tailing factor: NMT 1.5 for the cefaclor peak

Relative standard deviation: NMT 1.0% for the cefaclor peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefaclor ($C_{15}H_{14}ClN_3O_4S$) in the portion of Tablets taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

P = designated potency of USP Cefaclor RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **Dissolution ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 900 mL

Apparatus 1 (10-mesh basket)**:** 100 rpm

Time: 30, 60, and 240 min

Standard solution: 0.025 mg/mL of USP Cefaclor RS in *Medium*

Sample solution: Filtered portion of the solution under test, diluted with *Medium* to obtain a solution with an estimated concentration of 25 µg/mL of cefaclor

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

Mode: UV

Analytical wavelength: Maximum absorbance at about 265 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of cefaclor ($C_{15}H_{14}ClN_3O_4S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: The percentages of the labeled amount of cefaclor ($C_{15}H_{14}ClN_3O_4S$) dissolved at the times specified conform to *Table 1*.

Table 1

Time (min)	Amount Dissolved (%)
30	5–30
60	20–50
240	NLT 80

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

IMPURITIES

• **Organic Impurities**

Diluent: 2.4 g/L of monobasic sodium phosphate in water, adjusted with phosphoric acid to a pH of 2.5

Solution A: 6.9 g/L of monobasic sodium phosphate in water, adjusted with phosphoric acid to a pH of 4.0

Solution B: Acetonitrile and *Solution A* (45:55), degassing for NMT 2 min

Mobile phase: See *Table 2*.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	95	5
30	75	25
45	0	100
55	0	100
60	95	5
70	95	5

Standard solution: 0.05 mg/mL of USP Cefaclor RS in *Diluent*. Sonicate briefly, if necessary, to dissolve, and avoid heating. Use within 18 h if stored at room temperature, or within 24 h when stored at 5°.

System suitability solution: 0.05 mg/mL of USP Cefaclor RS and 0.05 mg/mL of USP Cefaclor Delta-3 Isomer RS in *Diluent*

Sample solution: Nominally 5 mg/mL of cefaclor from Tablets prepared as follows. Weigh and finely powder NLT 20 Tablets. Transfer a portion of the powder, containing nominally about 50 mg of cefaclor, to a 10-mL volumetric flask. Dissolve in *Diluent*, using brief sonication, if necessary, to achieve dissolution. Avoid heating. Dilute with *Diluent* to volume, mix, and filter. Use within 3 h if stored at room temperature, or within 20 h if stored at 5°.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for cefaclor and cefaclor delta-3 isomer are 1.0 and 0.85, respectively.]

Suitability requirements

Resolution: NLT 2.0 between cefaclor delta-3 isomer and cefaclor

Tailing factor: NMT 1.2 for the cefaclor peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each related compound in the portion of Tablets taken:

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

r_U = peak response of an individual related compound from the *Sample solution*

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

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

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

P = potency of USP Cefaclor RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria

Individual impurities: NMT 0.6% of any individual cefaclor related compound

Total impurities: NMT 2.0% of all cefaclor related compounds. Disregard any peak less than 0.1%.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers, and store at controlled room temperature.
- **USP REFERENCE STANDARDS ⟨11⟩**

USP Cefaclor RS

USP Cefaclor Delta-3 Isomer RS

(6*R*,7*R*)-7-{[(2*R*)-Aminophenylacetyl)]amino}-3-chloro-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-3-ene-2-carboxylic acid.

$C_{15}H_{14}ClN_3O_4S$ 367.80

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

Topic/Question	Contact	Expert Committee
CEFACLOR EXTENDED-RELEASE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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