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Cefaclor for Oral Suspension

DEFINITION

Cefaclor for Oral Suspension is a dry mixture of Cefaclor and one or more suitable buffers, colors, diluents, and flavors. It contains the equivalent of NLT 90.0% and NMT 120.0% 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 stock solution: Constitute Cefaclor for Oral Suspension as directed in the labeling, freshly mixed and free from air bubbles.

Sample solution: Nominally 0.3 mg/mL of cefaclor from *Sample stock solution* diluted with *Mobile phase*. Sonicate if necessary to ensure complete dissolution of the cefaclor, and 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 and cefaclor delta-3 isomer peaks

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 Cefaclor for Oral Suspension 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%–120.0%

PERFORMANCE TESTS

- **Deliverable Volume ⟨698⟩:** Meets the requirements

• **Uniformity of Dosage Units ⟨905⟩:** For solid packaged in single-unit containers, meets 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 1*.

Table 1

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 stock solution: Constitute Cefaclor for Oral Suspension as directed in the labeling, freshly mixed and free from air bubbles.

Sample solution: Nominally 5 mg/mL of cefaclor from *Sample stock solution* diluted with *Diluent*. Sonicate if necessary, avoid heating to ensure complete dissolution of the cefaclor, and filter. Use within 3 h if stored at room temperature, or within 20 h when 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 Cefaclor for Oral Suspension 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 cefaclor in USP Cefaclor RS (µg/mg)

F = conversion factor, 0.001 mg/µg

Acceptance criteria

Individual impurities: NMT 1.0% of any individual cefaclor related compound

Total impurities: NMT 3.0% of all cefaclor related compounds. Disregard any peak less than 0.1%.

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample: Suspension constituted as directed in the labeling

Acceptance criteria: 2.5–5.0

ADDITIONAL REQUIREMENTS

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

• **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 FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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