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Cephalexin for Oral Suspension

DEFINITION

Cephalexin for Oral Suspension is a dry mixture of Cephalexin 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 $C_{16}H_{17}N_3O_4S$ per 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**

Mobile phase: 0.985 g/L of sodium 1-pentanesulfonate in a mixture of acetonitrile, methanol, triethylamine, and water (20:10:3:170), adjusted with phosphoric acid to a pH of 3.0 ± 0.1

Standard stock solution: 1 mg/mL of USP Cephalexin RS in water

Standard solution: Mix 10.0 mL of *Standard stock solution* with 15.0 mL of *Mobile phase*.

Sample stock solution: Nominally equivalent to 1 mg/mL of cephalexin from Oral Suspension, constituted as directed in the labeling, freshly mixed and free from air bubbles. Sonicate, if necessary, to assure complete dissolution of the cephalexin. Filter, if necessary, to obtain a clear solution.

Sample solution: Mix 10.0 mL of *Sample stock solution* and 15.0 mL of *Mobile phase*.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1 of low acidity

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cephalexin ($C_{16}H_{17}N_3O_4S$) in each mL of the constituted 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 Cephalexin RS in the *Standard stock solution* (mg/mL)

C_U = nominal concentration of cephalexin from the *Sample stock solution* (mg/mL)

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

F = conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩** For solid packaged in single-unit containers: meets the requirements

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

SPECIFIC TESTS

• **pH ⟨791⟩:** 3.0–6.0, constituted as directed in the labeling

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Cephalexin RS

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

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

Chromatographic Database Information: Chromatographic Database

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