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

Delete the following:

•• **A. Thin-Layer Chromatography**
Standard solution: 3 mg/mL of USP Cephalexin RS in water
Sample solution: 3 mg/mL of Cephalexin, from Oral Suspension constituted as directed in the labeling and filtered
Ninhydrin solution: 66.7 mg/mL of ninhydrin in acetone
Chromatographic system
Mode: TLC
Adsorbent: 0.25-mm layer of binder-free silica gel
Application volume: 10 µL
Pre-developing solvent: *n*-Hexane and tetradecane (95:5)
Developing solvent: 0.1 M citric acid, 0.1 M dibasic sodium phosphate, and *Ninhydrin solution* (120:80:3)
Analysis
Samples: *Standard solution* and *Sample solution*
Place the plate in *Pre-developing solvent* at a depth of 1 cm and allow the solvent front to move the length of the plate, remove the plate from the chamber, and allow the solvent to evaporate. On this plate apply 10 µL each of the *Sample solution* and the *Standard solution*. Allow the spots to dry, and develop the chromatogram in the *Developing solvent* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, dry the plate for 10 min at 110°, and examine the chromatogram.
Acceptance criteria: The R_F value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*••$_S$

Add the following:

•• The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.••$_S$

ASSAY

Change to read:

• **Procedure**
Mobile phase: 0.985 g/L of sodium 1-pentanesulfonate in 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*.

••$_S$
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*
••$_S$
Suitability requirements
••$_S$
Relative standard deviation: NMT 2.0%
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of $C_{16}H_{17}N_3O_4S$ in each mL of Oral Suspension taken:

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

r_U = cephalexin peak response from the *Sample solution*
r_S = cephalexin 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 = designated potency of USP Cephalexin RS (µg/mg)
F = unit 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

Delete the following:

•• **Water Determination,** *Method I* ⟨**921**⟩**:** NMT 2.0%••$_S$
• **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

In-Process Revision

Date: 10-JUN-2010 Time: 8:22
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