Cephalexin Tablets for Oral Suspension

DEFINITION

Cephalexin Tablets for Oral Suspension contain NLT 90.0% and NMT 110.0% of the labeled amount of cephalexin ($C_{16}H_{17}N_3O_4S$).

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 powdered Tablets for Oral Suspension in water and filter

Chromatographic system

(See *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*.

Mode: TLC

Adsorbent: 0.25-mm layer of binder-free silica gel

Application volume: 10 µL

Pre-developing solvent system: *n*-Hexane and tetradecane (95:5)

Ninhydrin solution: 66.7 mg/mL of ninhydrin in acetone

Developing solvent system: 0.1 M citric acid, 0.1 M dibasic sodium phosphate, and *Ninhydrin solution* (60:40:1.5)

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the solvent front to move the length of the plate in the *Pre-developing solvent system*, remove the plate from the chamber, and allow the solvent to evaporate. On this plate apply 10 µL each of the *Standard solution* and *Sample solution*. Allow the spots to dry, and develop the chromatogram in the *Developing solvent system* 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 a mixture of acetonitrile, methanol, triethylamine, and water (20:10:3:170), adjusted with phosphoric acid to a pH of 3.0 ± 0.1

•$_S$

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

Standard solution: •0.4 mg/mL of cephalexin in *Mobile phase* from *Standard stock solution*•$_S$

Sample stock solution: Nominally equivalent to 1 mg/mL of cephalexin from combined contents of NLT 20 powdered Tablets for Oral Suspension in water. Pass a portion of the solution through a filter having a 1-µm or finer porosity.

Sample solution: •0.4 mg/mL of cephalexin in *Mobile phase* from *Sample stock solution*•$_S$

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 Tablet for Oral Suspension:

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

r_U = response from the *Sample solution*

r_S = response from the *Standard solution*•$_S$

C_S = concentration of USP Cephalexin RS in the *Sample stock solution* (mg/mL)

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

P = designated content of cephalexin in USP Cephalexin RS (µg/mg)

F = unit conversion factor, 0.001 mg/µg

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Disintegration** ⟨**701**⟩**:** Tablets for Oral Suspension disintegrate in 3 min, using water at 20 ± 5°.

• **Dissolution** ⟨**711**⟩

Medium: Water; 900 mL

Apparatus 1: Use 40-mesh cloth and 100 rpm

Time: 30 min

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium*, if necessary, to a concentration of about 20 µg/mL.

Standard solution: 20 µg/mL of USP Cephalexin RS in *Medium*

Spectrometric conditions

(See *Spectrophotometry and Light-Scattering* ⟨851⟩.)

Mode: UV

Analytical wavelength: 262 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Tolerances: NLT 80% (Q) of the labeled amount of $C_{16}H_{17}N_3O_4S$ is dissolved.

• **Dispersion Fineness:** Place 2 Tablets for Oral Suspension in 100 mL of water, and stir until completely dispersed. A smooth dispersion is obtained that passes through a No. 25 sieve.

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

SPECIFIC TESTS

Delete the following:

•• **Water Determination,** *Method I* ⟨**921**⟩**:** NMT 9.0%•$_S$

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers at controlled room temperature.

• **USP Reference Standards** ⟨**11**⟩

USP Cephalexin RS

In-Process Revision

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