Cephalexin Capsules

DEFINITION

Cephalexin Capsules contain the equivalent of NLT 90.0% and NMT 120.0% 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 Capsules 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 *Sample solution* and *Standard 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: Equivalent to 1 mg/mL of cephalexin from combined contents of NLT 20 Capsules in water. Sonicate, if necessary, to dissolve the cephalexin. Filter, if necessary, to obtain a clear solution.
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 the portion of Capsules taken:

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

r_U = response from the *Sample solution*
r_S = response from the *Standard solution*••$_S$
C_S = concentration of USP Cephalexin RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of cephalexin in the *Sample 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%–120.0%

PERFORMANCE TESTS

• **Dissolution** ⟨**711**⟩
Medium: Water; 900 mL
Apparatus 1: 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.
• **Uniformity of Dosage Units** ⟨**905**⟩**:** Meet the requirements

SPECIFIC TESTS

Delete the following:

•• **Water Determination,** *Method I* ⟨**921**⟩**:** NMT 10.0%••$_S$

ADDITIONAL REQUIREMENTS

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

In-Process Revision

Date: 11-JUN-2010 Time: 7:21
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