Cephalexin Tablets

DEFINITION

Cephalexin Tablets are prepared from Cephalexin or Cephalexin Hydrochloride. They 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:

•• **THIN-LAYER CHROMATOGRAPHY**
Standard solution: 3 mg/mL of USP Cephalexin RS in water
Sample solution: 3 mg/mL of cephalexin from powdered Tablets 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). Adjust 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 powdered Tablets (NLT 20) in water. Sonicate, if necessary, to assure complete dissolution of 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 Tablets 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*•$_S$
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**⟩
For Cephalexin
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, if necessary, with *Medium* to a concentration that is similar to the *Standard solution.*
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.
For Cephalexin hydrochloride
Medium, Sample solution, Standard solution, Spectrometric conditions, and **Analysis:** Proceed as directed *For Cephalexin.*
Apparatus 1: Use 10-mesh cloth and 150 rpm
Time: 45 min
Tolerances: NLT 75% (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 9.0% where Tablets contain Cephalexin; NMT 8.0% where Tablets contain Cephalexin Hydrochloride•$_S$

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.
• **LABELING:** The label states whether the Tablets contain Cephalexin or Cephalexin Hydrochloride.
• **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Cephalexin RS

In-Process Revision

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