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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

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). Adjust 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: 0.4 mg/mL of cephalexin in *Mobile phase* from *Standard stock solution*

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*

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 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*

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 = potency of cephalexin in USP Cephalexin RS (µg/mg)

F = 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

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

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.*

Spectrometric conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Analytical wavelength: 262 nm

Analysis

Samples: *Standard solution* and *Sample solution*

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

For Cephalexin hydrochloride

Medium, Standard solution, Sample 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 cephalexin ($C_{16}H_{17}N_3O_4S$) is dissolved.

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

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

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

Topic/Question	Contact	Expert Committee
CEPHALEXIN TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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