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## 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

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), adjusted with phosphoric acid to a pH of  $3.0 \pm 0.1$

**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 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*

#### Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm  $\times$  25-cm; packing L1 of low acidity

**Flow rate:** 1.5 mL/min

**Injection size:** 20  $\mu$ L

#### 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 Capsules 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](#) ( $\mu$ g/mg)

$F$  = conversion factor, 0.001 mg/ $\mu$ g

**Acceptance criteria:** 90.0%–120.0%

### PERFORMANCE TESTS

#### • DISSOLUTION (711)

**Medium:** Water; 900 mL

**Apparatus 1:** 100 rpm

**Time:** 30 min

**Standard solution:** 20  $\mu$ g/mL of [USP Cephalexin RS](#) in *Medium*

**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  $\mu$ g/mL.

**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.

- **[UNIFORMITY OF DOSAGE UNITS \(905\)](#):** Meet the requirements

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- **[USP REFERENCE STANDARDS \(11\)](#).**

[USP Cephalexin RS](#)

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**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

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