

Status: Currently Official on 14-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: USP Monographs
 DocId: GUID-D32532EA-9097-4AA5-BB33-8667DD0A074F_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M323_01_01
 DOI Ref: v5v4x

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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

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 ± 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: 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- μ m or finer pore size.

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 μ 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 each Tablet for Oral Suspension:

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

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 stock solution* (mg/mL)

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

P = potency of cephalexin in [USP Cephalexin RS](#) (μ g/mg)

F = conversion factor, 0.001 mg/ μ g

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISINTEGRATION \(701\)](#): Tablets for Oral Suspension disintegrate in 3 min, using water at $20 \pm 5^\circ$.

• [DISSOLUTION \(711\)](#)

Medium: Water; 900 mL

Apparatus 1: Use 40-mesh cloth and 100 rpm.

Time: 30 min

Standard solution: 20 μ 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 µg/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.

- **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

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers at controlled room temperature.
- **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 FOR ORAL SUSPENSION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 36(1)

Current DocID: GUID-D32532EA-9097-4AA5-BB33-8667DD0A074F_1_en-US

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