**UNIFORMITY OF DOSAGE UNITS**

**Medium:** USP 35

**LABELING:**

**PERFORMANCE TESTS**

- **Dissolution** (711)
  - For Cephalexin Hydrochloride
    - **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 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 cephalexin (C₁₆H₁₇N₃O₄S) 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 (C₁₆H₁₇N₃O₄S) is dissolved.
  - **Uniformity of Dosage Units** (905): Meet the requirements

**USP REFERENCE STANDARDS** (11)

**USP Cephalexin RS**

**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 (C₁₆H₁₇N₃O₄S).

**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 NL T 20 powdered Tablets for Oral Suspension in water. Pass a portion of the solution through a filter having a 1-µm 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 × 25-cm; packing L1 of low acidity
    - **Flow rate:** 1.5 mL/min
    - **Injection size:** 20 µL

  **Spectrometric conditions**
  - **Injection size:** 20 µL
  - **Mode:** UV
  - **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
  - **Tolerances:** NLT 80% (Q) of the labeled amount of cephalexin (C₁₆H₁₇N₃O₄S) 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.
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 cephalixin (C₁₆H₁₃N₂O₆S₂) is dissolved.

**Dispersion Finessness:** 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

**Specific Tests**

**Additional Requirements**
• **Packaging and Storage:** Preserve in tight containers at controlled room temperature.
• **USP Reference Standards (11)** USP Cephalexin RS

**Cephalothin Sodium**

C₁₆H₁₅N₄O₆S₂ 418.42
5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-
[(acetyloxy)methyl]-8-oxo-7-[2-thienylacetyl]amino]-
monosodium salt, (6R-trans).
Monosodium (6R,7R)-3-(hydroxymethyl)-8-oxo-7-[2-(2-thienyl)
-acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate
acetate (ester) [58-71-9].

» Cephalothin Sodium contains the equivalent of not less than 850 μg of cephalothin (C₁₆H₁₅N₄O₆S₂) per mg, calculated on the dried basis.

**Packaging and storage**—Preserve in tight containers.

**Labeling**—Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

**USP Reference Standards (11)**—
USP Cephalothin Sodium RS

**USP Endotoxin RS**

**Chromatographic purity**

**Mobile phase,** Resolution solution, and Chromatographic system—Proceed as directed in the Assay.

**Standard solution**—Use the Standard preparation, prepared as directed in the Assay, transfer 1.0 mL to a 100-mL volumetric flask, dilute with Mobile phase to volume, and mix.

**Test solution**—Use the Assay preparation prepared as directed in the Assay.

**Procedure**—Proceed as directed for the Procedure in the Assay, except to inject equal volumes (about 20 μL) of the Standard solution and the Test solution and to continue the chromatography of the Test solution for at least 4 times the retention time of the main cephalothin peak. The area of any peak in the chromatogram obtained from the Test solution, except the main peak, is not greater than the area of the main peak in the chromatogram obtained from the Standard solution (1.0%), and the sum of the areas of any such peaks is not greater than 3 times the area of the main peak in the chromatogram obtained from the Standard solution (3.0%). [NOTE—Any peak in the chromatogram obtained from the Test solution with an area less than one-tenth that of the main peak in the chromatogram obtained from the Standard solution is disregarded.]

**Other requirements**—Where the label states that Cephalothin Sodium is sterile, it meets the requirements for Sterility and Bacterial endotoxins under Cephalothin for Injection. Where the label states that Cephalothin Sodium must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for Bacterial endotoxins under Cephalothin for Injection.

**Assay**

**Mobile phase**—Dissolve 17 g of sodium acetate in 790 mL of water, add 0.6 mL of glacial acetic acid, and if necessary adjust with 0.1 N sodium hydroxide or glacial acetic acid to a pH of 5.9 ± 0.1. Add 150 mL of acetonitrile and 70 mL of alcohol, and mix. Make adjustments if necessary (see System Suitability under Chromatography (621)).

**Standard preparation**—Dissolve an accurately weighed quantity of USP Cephalothin Sodium RS quantitatively in Mobile phase to obtain a solution having a known concentration of about 1 mg per mL.

**Resolution solution**—Heat a 5-mL portion of the Standard preparation in a water bath at 90 °C for 10 minutes. Cool the solution, and immediately inject a portion of it into the chromatograph as directed under Chromatographic system.

**Assay preparation**—Transfer about 25 mg of Cephalothin Sodium, accurately weighed, to a 25-mL volumetric flask, add about 15 mL of Mobile phase, swirl to dissolve, dilute with Mobile phase to volume, and mix.

**Chromatographic system** (see Chromatography (621))—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains 5 μm packing L1 and is maintained at a constant temperature of about 40 °C. The flow rate is about 1 mL per minute. Chromatograph the Resolution solution, and record the peak responses as directed under Procedure: the resolution between the two principal peaks is not less than 9.0. Chromatograph the Standard preparation, and record the peak responses as directed under Procedure: the tailing factor is not more than 1.8, and the relative standard deviation for replicate injections is not more than 1.0%.

**Procedure**—[NOTE—Use peak areas where peak responses are indicated.] Separately inject equal volumes (about 20 μL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in μg, of cephalothin (C₁₆H₁₅N₄O₆S₂) in each mg of Cephalothin Sodium taken by the formula:

\[
25CP/W(t_0/t_r)
\]

in which \( C \) is the concentration, in mg per mL, of USP Cephalothin Sodium RS in the Standard preparation; \( P \) is the assigned potency, in μg of cephalothin per mg, of USP Cephalothin So-