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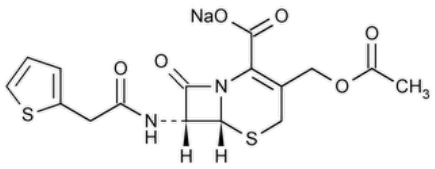
Cephalothin Sodium



$C_{16}H_{15}N_2NaO_6S_2$ 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, (6*R*-*trans*)-. Monosodium (6*R*,7*R*)-3-(hydroxymethyl)-8-oxo-7-[2-(2-thienyl)-acetamido]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate acetate (ester) CAS RN®: 58-71-9; UNII: C22G6EYP8B.

» Cephalothin Sodium contains the equivalent of not less than 850 µg of cephalothin ($C_{16}H_{16}N_2O_6S_2$) 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

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: 25 µg per mL.

Medium: water.

B: It responds to the tests for *Sodium* ⟨191⟩.

Specific rotation ⟨781S⟩: between +124° and +134°.

Test solution: a known amount of specimen, equivalent to about 50 mg of cephalothin, per mL, in water.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 4.5 and 7.0, in a solution containing 250 mg per mL.

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 1.5% of its weight.

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° 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°. 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 ($C_{16}H_{16}N_2O_6S_2$) in each mg of Cephalothin Sodium taken by the formula:

$$25(CP/W)(r_U/r_S)$$

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 Sodium RS; W is the quantity, in mg, of Cephalothin Sodium taken to prepare the *Assay preparation*; and r_U and r_S are the cephalothin peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
CEPHALOTHIN SODIUM	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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