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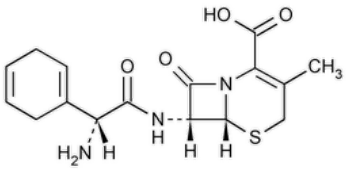
Cephradine



$C_{16}H_{19}N_3O_4S$ 349.40

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[(amino-1,4-cyclohexadien-1-ylacetyl)amino]-3-methyl-8-oxo-, [6*R*-[6α,7β(*R**)]]-.

(6*R*,7*R*)-7-[(*R*)-2-Amino-2-(1,4-cyclohexadien-1-yl)acetamido]-3- methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid CAS RN®: 38821-53-3.

Monohydrate 367.43 CAS RN®: 31828-50-9 (non-stoichiometric hydrate).

Dihydrate 385.44 CAS RN®: 58456-86-3.

» Cephradine has a potency of not less than 900 µg and not more than 1050 µg of total cephalosporins per mg, calculated as the sum of cephradine ($C_{16}H_{19}N_3O_4S$) and cephalexin ($C_{16}H_{17}N_3O_4S$), calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers.

Labeling—Where it is the dihydrate form, the label so indicates. Where the quantity of cephradine is indicated in the labeling of any preparation containing Cephradine, this shall be understood to be in terms of anhydrous cephradine ($C_{16}H_{19}N_3O_4S$). 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 Cephradine RS
USP Cephalexin RS

Change to read:

▲**Spectroscopic Identification Tests** ⟨197⟩, *Infrared Spectroscopy*: 197K.▲ (CN 1-May-2020)

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 3.5 and 6.0, in a solution containing 10 mg per mL.

Water Determination, *Method I* ⟨921⟩: not more than 6.0%, except that if it is the dihydrate form, the limit is between 8.5% and 10.5%.

Limit of cephalexin—Using the chromatogram of the *Assay preparation* obtained in the *Assay*, calculate the percentage of cephalexin ($C_{16}H_{17}N_3O_4S$) in the portion of Cephradine taken by the formula:

$$100(r_{Ux}/r_U)$$

in which r_{Ux} is the cephalexin peak response in the chromatogram obtained from the *Assay preparation*, and r_U is the sum of the cephalexin and cephradine peak responses in the chromatogram obtained from the *Assay preparation:* not more than 5.0%, calculated on the anhydrous basis, is found.

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

Assay—

Mobile phase—Prepare a mixture of water, methanol, 0.5 M sodium acetate, and 0.7 N acetic acid (782:200:15:3). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). Filter the solution through a filter of 1 µm or finer porosity, and degas before use.

Standard preparation—Dissolve an accurately weighed quantity of USP Cephradine RS quantitatively in *Mobile phase* to obtain a solution having a known concentration of about 0.5 mg per mL.

Resolution solution—Prepare a solution in *Mobile phase* containing in each mL about 0.5 mg of USP Cephradine RS and 0.5 mg of USP Cephalexin RS.

Assay preparation—Transfer about 50 mg of Cephradine, accurately weighed, to a 100-mL volumetric flask, add about 30 mL of *Mobile phase*, and sonicate. 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 packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed under *Procedure:* the relative retention times are about 0.8 for cephalexin and 1.0 for cephradine; and the resolution, *R,* between the cephalexin peak and the cephradine peak is not less than 2.0. Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 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 total cephalosporins (sum of cephradine and cephalexin) in each mg of the Cephradine taken by the formula:

$$100(CP/M)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Cephradine RS in the *Standard preparation*; P is the designated potency, in µg per mg, of USP Cephradine RS; M is the quantity, in mg, of Cephradine taken to prepare the *Assay preparation*; and r_U and r_S are the sums of the cephradine and cephalexin 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
CEPHRADINE	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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

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