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## Cefmetazole

 $C_{15}H_{17}N_7O_5S_3$  471.53

5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(cyanomethyl)thio]acetyl]amino]-7-methoxy-3- [[(1-methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-, (6*R-cis*)-.

(6R,7S)-7-[2-[(Cyanomethyl)thio]acetamido]-7-methoxy- 3-[[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid CAS RN $^{(8)}$ : 56796-20-4; UNII: 3J962UJT8H.

» Cefmetazole contains not less than 970  $\mu$ g and not more than 1030  $\mu$ g of cefmetazole ( $C_{15}H_{17}N_7O_5S_3$ ) per mg, calculated on the anhydrous

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)

**USP Cefmetazole RS** 

Identification-

## Change to read:

A: <sup>≜</sup>Spectroscopic Identification Tests (197), Infrared Spectroscopy: 197M<sub>▲</sub> (CN 1-May-2020)

**B:** The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

**WATER DETERMINATION,** *Method I* (921): not more than 0.5%.

## Assay-

Mobile phase—Dissolve 5.75 g of monobasic ammonium phosphate in 700 mL of water, add 3.2 mL of a 40% solution of tetrabutylammonium hydroxide, 280 mL of methanol, and 25 mL of tetrahydrofuran, and mix. Adjust with phosphoric acid to a pH of 4.5  $\pm$  0.1, pass through a filter having a 0.5- $\mu$ m or finer porosity, and degas. Make adjustments if necessary (see <u>System Suitability</u> under <u>Chromatography (621)</u>). Standard preparation—Quantitatively dissolve an accurately weighed quantity of <u>USP Cefmetazole RS</u> in <u>Mobile phase</u> to obtain a solution having a known concentration of about 200  $\mu$ g of cefmetazole ( $C_{15}H_{17}N_7O_5S_3$ ) per mL. [Note—Use this solution within 10 minutes.]

Resolution solution—Prepare a solution of <u>USP Cefmetazole RS</u> in 0.01 N sodium hydroxide containing about 1 mg per mL. Heat at 95° for 10 minutes. To 1 mL of this solution add 2 mL of *Standard preparation*, and dilute with *Mobile phase* to obtain 20 mL of solution. This solution contains cefmetazole and cefmetazole lactone (resolution compound).

Assay preparation—Transfer about 20 mg of Cefmetazole, accurately weighed, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. [Note—Use this solution within 10 minutes.]

Chromatographic system (see Chromatography (621))—The liquid chromatograph is equipped with a 214-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the Resolution solution, and record the peak responses as directed for Procedure: the resolution, R, between cefmetazole and cefmetazole lactone is not less than 3.0. Chromatograph the Standard preparation, and record the peak responses as directed for Procedure: the column efficiency is not less than 1250 theoretical plates; the tailing factor is not less than 0.94 and not more than 1.6; and the relative standard deviation for replicate injections is not more than 2.0%. Procedure—Separately inject equal volumes (about 10  $\mu$ L) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in  $\mu$ g, of cefmetazole ( $C_{15}H_{17}N_7O_5S_3$ ) in each mg of Cefmetazole taken by the formula:

$$100(C/M)(r_{_{I}}/r_{_{S}})$$

in which C is the concentration, in  $\mu$ g per mL, of cefmetazole ( $C_{15}H_{17}N_7O_5S_3$ ) in the *Standard preparation; M* is the quantity, in mg, of Cefmetazole taken to prepare the *Assay preparation;* and  $r_S$  are the cefmetazole peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

 ${\bf Chromatographic\ Database\ Information:\ } \underline{{\bf Chromatographic\ Database}}$ 

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