

$$T_1 = \text{Percent MMT (tetrazole)} = \frac{A_u \times C_s \times P_s \times 100}{A_s \times C_u \times 1,000}$$

$$T_2 = \text{Percent related compound} = \frac{R_u \times C_s \times P_s \times 100}{R_s \times C_u \times 1,000}$$

$$L = \text{Percent largest related compound} = \frac{L_u \times C_s \times P_s \times 100}{R_s \times C_u \times 1,000}$$

where:

A_u =Area of the tetrazole sample peak;

A_s =Area of the tetrazole working standard peak;

C_s =Concentration of the working standard in milligrams per milliliter;

P_s =Potency of the working standard in micrograms per milligram;

C_u =Concentration of the sample solutions in milligrams per milliliter;

R_u =Sum of peak areas of other compounds, excepting MMT and cefpiramide, detected in the sample chromatogram.

R_s =Area of the cefpiramide working standard peak; and

L_u =Area of the largest related peak, except MMT.

T =Percent total related compounds= $T_1 + T_2$.

(5) *Specific rotation.* Dilute an accurately weighed sample with sufficient dimethylformamide to obtain a concentration of approximately 10 milligrams of cefpiramide per milliliter. Proceed as directed in §436.210 of this chapter, using a 1-decimeter polarimeter tube. Calculate the specific rotation on the anhydrous basis.

(6) *Identify.* Proceed as directed in §436.211 of this chapter using a 1-percent potassium bromide disc prepared as directed in §436.211(b)(1).

(7) *Crystallinity.* Proceed as directed in §436.203(a) of this chapter.

[55 FR 14240, Apr. 17, 1990]

§ 442.69 Cefmetazole.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Cefmetazole is (6*R*,7*S*)-7-[2-[(cyanomethyl)thio]acetamido]-7-methoxy-3-[[1-(methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is so purified and dried that:

(i) Its potency is not less than 970 micrograms of cefmetazole activity per milligram.

(ii) Its moisture content is not more than 0.5 percent.

(iii) It gives a positive identity test for cefmetazole.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, moisture, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research: 10 packages each containing approximately 500 milligrams.

(b) *Tests and methods of assay—(1) Potency.* Proceed as directed in §442.70a(b)(1).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *Identity.* Proceed as directed in §436.211 of this chapter using a mineral oil mull prepared as described in paragraph (b)(2) of that section.

[59 FR 12546, Mar. 17, 1994]

§ 442.70a Sterile cefmetazole sodium.

(a) *Requirements for certification—(1) Standards of identity, strength, quality, and purity.* Sterile cefmetazole sodium is the sodium salt of (6*R*-cis)-7-[[[cyanomethyl]thio]acetyl]amino]-7-methoxy-3-[[1-(methyl-1*H*-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid. It is a lyophilized powder. It is so purified and dried that:

(i) If the cefmetazole sodium is not packaged for dispensing, its