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Trientine Hydrochloride Capsules

» Trientine Hydrochloride Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_6H_{18}N_4 \cdot 2HCl$.

Packaging and storage—Preserve in tight containers, and store in a refrigerator.

USP Reference standards ⟨11⟩—

USP Trientine Hydrochloride RS

Identification—Triturate an amount of the contents of Capsules, equivalent to about 1.5 mg of trientine hydrochloride, with 0.5 mL of acetone in an agate or mullite mortar. Evaporate in a gentle current of air to dryness. Repeat the acetone addition, trituration, and drying steps: the IR absorption spectrum of a potassium bromide dispersion of the residue so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Trientine Hydrochloride RS.

Dissolution ⟨711⟩—

Medium: water; 500 mL.

Apparatus 2: 50 rpm.

Time: 30 minutes.

pH 8.2 buffer—Prepare as directed under *Assay*.

Copper sulfate reagent—Mix 10 mL of copper sulfate solution (5 g copper sulfate pentahydrate in 100 mL of water) with 40 mL of *pH 8.2 buffer*. [NOTE—The solution must be clear.]

Standard preparation—Dissolve an accurately weighed quantity of USP Trientine Hydrochloride RS in water to obtain a solution having a known concentration of about 0.5 mg per mL.

Procedure—Pipet an aliquot of a filtered portion of the solution under test, estimated to contain about 5 mg of trientine hydrochloride, into a 50-mL centrifuge tube. Into a similar centrifuge tube, pipet an equivalent volume of water to provide a reagent blank, and into a third centrifuge tube pipet 10 mL of *Standard preparation*. Into each tube, pipet 5 mL of *Copper sulfate reagent*, stopper, and mix immediately using a vortex mixer. Determine the absorbances of the solutions from the *Standard preparation* and the test solution at 580 and 410 nm, with a suitable spectrophotometer, against the reagent blank. Calculate the quantity in mg of trientine hydrochloride dissolved by the formula:

$$5000(C/V)[(A_U - A_{UX})/(A_S - A_{SX})]$$

in which C is the concentration, in mg per mL, of USP Trientine Hydrochloride RS in the *Standard preparation*, V is the volume, in mL, of the aliquot of test solution used, A_U and A_S are the absorbances at 580 nm of test and standard solutions, respectively, and A_{UX} and A_{SX} are the absorbances at 410 nm of test and standard solutions, respectively.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_6H_{18}N_4 \cdot 2HCl$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Copper reagent—Dissolve 5 g of copper sulfate pentahydrate in water to make 100 mL, and mix.

pH 8.2 buffer—Dissolve 20.74 g of anhydrous dibasic sodium phosphate, 6.72 g of anhydrous citric acid, and 0.535 g of monobasic sodium phosphate in 400 mL of water, adjust with sodium hydroxide solution (1 in 2) to a pH of 8.2 ± 0.05, dilute with water to make 500 mL, and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Trientine Hydrochloride RS in methanol to obtain a solution having a known concentration of about 2.5 mg per mL. Transfer 5.0 mL of this solution to a glass-stoppered, 50-mL conical flask.

Assay preparation—Remove, as completely as possible, the contents of not less than 20 Capsules. Weigh the contents, and determine the average weight per capsule. Mix the combined contents, and transfer an accurately weighed quantity of the powder, equivalent to about 250 mg of trientine hydrochloride, to a 100-mL volumetric flask. Add about 70 mL of methanol, and shake or sonicate to dissolve. Dilute with methanol to volume, mix, and filter, discarding the first few mL of the filtrate. Transfer 5.0 mL of this solution to a glass-stoppered, 50-mL conical flask.

Procedure—To each of the flasks containing the *Standard preparation* and the *Assay preparation* and to a similar flask containing 5.0 mL of methanol to provide the blank, add 10.0 mL of *pH 8.2 buffer* and 1.0 mL of *Copper reagent*, and mix. Concomitantly determine the

absorbances of the solutions at the wavelength of maximum absorbance at about 580 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_6H_{18}N_4 \cdot 2HCl$ in the portion of Capsules taken by the formula:

$$100C(A_U/A_S)$$

in which C is the concentration, in mg per mL, of USP Trientine Hydrochloride RS in the *Standard preparation*, and A_U and A_S are the absorbances of the solutions 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
TRIENTINE HYDROCHLORIDE CAPSULES	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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