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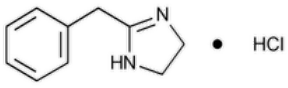
Tolazoline Hydrochloride



$C_{10}H_{12}N_2 \cdot HCl$ 196.68

1*H*-Imidazole, 4,5-dihydro-2-(phenylmethyl)-, monohydrochloride.

2-Benzyl-2-imidazoline monohydrochloride CAS RN®: 59-97-2; UNII: E669Z6S1JG.

» Tolazoline Hydrochloride contains not less than 98.0 percent and not more than 101.0 percent of $C_{10}H_{12}N_2 \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers. Store at 25°, excursions permitted between 15° and 30°.

USP Reference standards ⟨11⟩—
USP Tolazoline Hydrochloride RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197M*▲ (CN 1-May-2020) ·

B: The R_F value of the principal spot in the chromatogram of the *Identification* corresponds to that of *Standard solution A,* as obtained in the test for *Chromatographic purity.*

Melting range ⟨741⟩**:** between 172.0° and 176.0°.

Loss on drying ⟨731⟩—Dry it in vacuum over silica gel for 4 hours: it loses not more than 0.2% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Chromatographic purity—

Standard solutions—Dissolve USP Tolazoline Hydrochloride RS in methanol, and mix to obtain *Standard solution A* having a known concentration of 100 µg per mL. Quantitatively dilute with methanol to obtain *Standard solutions,* designated below by letter, having the following compositions:

Standard solution	Dilution	Concentration (µg RS per mL)	Percentage (%, for comparison with test specimen)
A	undiluted	100	0.5
B	4 in 5	80	0.4
C	3 in 5	60	0.3
D	2 in 5	40	0.2
E	1 in 5	20	0.1

Test solution—Dissolve an accurately weighed quantity of Tolazoline Hydrochloride in methanol to obtain a solution containing 20 mg per mL.
Identification solution—Quantitatively dilute a portion of the *Test solution* with methanol to obtain a solution containing 100 µg per mL.
Detection reagent—Prepare (1) a solution of 0.5 g of potassium iodide in 50 mL of water, and (2) a solution of 1.5 g of soluble starch in 50 mL of boiling water. Just prior to use, mix 10 mL of each solution with 3 mL of alcohol.

Procedure—Apply separately 5 µL of the *Test solution,* 5 µL of the *Identification solution,* and 5 µL of each *Standard solution* to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel. Position the plate in a chromatographic chamber, and develop the chromatograms in a solvent system consisting of a mixture of methanol and ammonium hydroxide (95:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the plate to dry under a current of warm air for at least 30 minutes. Expose the plate to chlorine gas for not more than 5 minutes, and air-dry until the chlorine has dissipated (about 15 minutes). Spray the plate with *Detection reagent,* and immediately compare the intensities of any secondary spots observed in the chromatogram of the *Test solution* with those of the principal spots in the chromatograms of the *Standard solutions:* the sum of the intensities of all secondary spots obtained from the *Test solution* corresponds to not more than 1.0%.

Assay—Dissolve about 300 mg of Tolazoline Hydrochloride, accurately weighed, in 100 mL of glacial acetic acid; add 25 mL of mercuric acetate TS; and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically (see *Titrimetry* ⟨541⟩), using a calomel–glass electrode system. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 19.67 mg of $C_{10}H_{12}N_2 \cdot HCl$.

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

Topic/Question	Contact	Expert Committee
TOLAZOLINE HYDROCHLORIDE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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