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Tolazoline Hydrochloride Injection

» Tolazoline Hydrochloride Injection is a sterile solution of Tolazoline Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{10}H_{12}N_2 \cdot HCl$.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩—
USP Tolazoline Hydrochloride RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) —Obtain the test specimen as follows. Steam-distill a volume of Injection, equivalent to about 250 mg of tolazoline hydrochloride, for 5 to 10 minutes, and discard the distillate. Transfer the remaining solution to a separator, add about 2 mL of 1 N sodium hydroxide, and extract with 20 mL of ether. Filter the ether extract through cotton into a beaker, evaporate to dryness, and dry the residue in vacuum over silica gel for 4 hours.

B: It responds to *Identification* test *B* under *Tolazoline Hydrochloride.*

C: To 1 mL of Injection add 1 mL of ammonium reineckate TS: a pink precipitate is formed.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.8 USP Endotoxin Unit per mg of tolazoline hydrochloride.

pH ⟨791⟩**:** between 3.0 and 4.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Assay—

Standard preparation—Transfer about 30 mg of USP Tolazoline Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, dissolve in and dilute with methanol to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 150 mg of tolazoline hydrochloride, to a 100-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 20.0 mL of this solution to a second 100-mL volumetric flask, dilute with methanol to volume, and mix.

Procedure—Transfer 3.0 mL each of the *Standard preparation*, the *Assay preparation*, and methanol to provide the blank, to separate 25-mL volumetric flasks. To each flask add 1 mL of 0.5 N sodium hydroxide and 1 mL of dilute sodium nitroferricyanide TS (1 in 2), mix, and allow to stand for 10 minutes. Add 3 mL of sodium bicarbonate solution (1 in 12) to each flask, dilute with water to volume, mix, and allow to stand for 10 minutes. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 565 nm, with a suitable spectrophotometer, against the blank. Calculate the quantity, in mg, of $C_{10}H_{12}N_2 \cdot HCl$ in each mL of the Injection taken by the formula:

$$(0.5C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Tolazoline Hydrochloride RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, 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
TOLAZOLINE HYDROCHLORIDE INJECTION	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

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