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Triflupromazine Hydrochloride Injection

» Triflupromazine Hydrochloride Injection is a sterile solution of Triflupromazine Hydrochloride in Water for Injection. It contains not less than 90.0 percent and not more than 112.0 percent of the labeled amount of $C_{18}H_{19}F_3N_2S \cdot HCl$.

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

USP Reference standards ⟨11⟩—
USP Triflupromazine Hydrochloride RS

[Note—Throughout the following procedures, protect test or assay specimens, the Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.]

Identification—

A: Place a volume of Injection, equivalent to about 100 mg of triflupromazine hydrochloride, in a test tube, add 5 mL of 8 N nitric acid, and mix: a peach to amber color develops, quickly turns dark brown, and then changes to a clear solution having a yellow tint.

B: A volume of Injection, equivalent to about 50 mg of triflupromazine hydrochloride, meets the requirements under *Identification—Organic Nitrogenous Bases ⟨181⟩*.

C: The UV absorption spectrum of the *Assay preparation*, prepared as directed in the *Assay*, exhibits maxima and minima at the same wavelengths as that of the *Standard preparation*, prepared as directed in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 5.8 USP Endotoxin Units per mg of triflupromazine hydrochloride.

pH ⟨791⟩: between 3.5 and 5.2.

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

Assay—

Standard preparation—Transfer about 50 mg of USP Triflupromazine Hydrochloride RS, accurately weighed, to a 50-mL volumetric flask, dissolve in 0.5 N sulfuric acid, dilute with 0.5 N sulfuric acid to volume, and mix. Proceed as directed under *Assay preparation*, beginning with "Transfer 10.0 mL of this solution to a 100-mL volumetric flask." The concentration of USP Triflupromazine Hydrochloride RS in the *Standard preparation* is about 5 µg per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of triflupromazine hydrochloride, to a 50-mL volumetric flask, dilute with 0.5 N sulfuric acid to volume, and mix. Transfer 10.0 mL of this solution to a 100-mL volumetric flask, dilute with the same acid to volume, and mix. Transfer 10.0 mL of this solution to a glass-stoppered, 50-mL centrifuge tube containing 10 mL of ether previously chilled in an ice bath, insert the stopper, shake for 3 minutes, and centrifuge at 1500 rpm for 5 minutes. Transfer 5.0 mL of the aqueous layer to a 100-mL volumetric flask, dilute with 0.5 N sulfuric acid to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparation* in 1-cm cells at the wavelength of maximum absorbance at about 255 nm, with a suitable spectrophotometer, using 0.5 N sulfuric acid as the blank. Calculate the quantity, in mg, of $C_{18}H_{19}F_3N_2S \cdot HCl$ in each mL of the Injection taken by the formula:

$$(10C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Triflupromazine 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 *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
TRIFLUPROMAZINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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