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Trifluoperazine Hydrochloride Injection

» Trifluoperazine Hydrochloride Injection is a sterile solution of Trifluoperazine Hydrochloride in Water for Injection. It contains an amount of trifluoperazine hydrochloride ($C_{21}H_{24}F_3N_3S \cdot 2HCl$) equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of trifluoperazine ($C_{21}H_{24}F_3N_3S$).

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

USP Reference standards ⟨11⟩—
USP Trifluoperazine 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: The solution employed for measurement of absorbance in the *Assay* exhibits UV maxima and minima at the same wavelengths as that of a similar solution of USP Trifluoperazine Hydrochloride RS, concomitantly measured.

B: Mix 5 mL of it with 5 mL of methanol: a 5-µL portion of this solution responds to *Identification* test *D* under *Trifluoperazine Hydrochloride.*

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 172.0 USP Endotoxin Units per mg of trifluoperazine.

pH ⟨791⟩: between 4.0 and 5.0.

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

Assay—[Note—Use low-actinic glassware.] Transfer an accurately measured volume of Injection, equivalent to about 20 mg of trifluoperazine, to a 250-mL separator. Add 10 mL of 4 N sulfuric acid, and extract with three 25-mL portions of carbon tetrachloride. Discard the carbon tetrachloride after each extraction. Add 10 mL of ammonium hydroxide, and extract with five 40-mL portions of cyclohexane. Extract the combined cyclohexane extracts with five 50-mL portions of 0.1 N hydrochloric acid, collecting the aqueous extracts in a 500-mL volumetric flask. Dilute with 0.1 N hydrochloric acid to volume, and mix. Transfer 25.0 mL of this solution to a 100-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix. Concomitantly determine the absorbances of this solution and of a Standard solution of USP Trifluoperazine Hydrochloride RS in the same medium having a known concentration of about 12 µg per mL in 1-cm cells at 278 nm and at the maximum at about 255 nm, with a suitable spectrophotometer, using 0.1 N hydrochloric acid as the blank. Calculate the quantity, in mg, of trifluoperazine ($C_{21}H_{24}F_3N_3S$) in each mL of the Injection taken by the formula:

$$(407.51/480.43)(2C/V)(A_{255} - A_{278})_U/(A_{255} - A_{278})_S$$

in which 407.51 and 480.43 are the molecular weights of trifluoperazine and trifluoperazine hydrochloride, respectively, C is the concentration, in µg per mL, of USP Trifluoperazine Hydrochloride RS in the Standard solution, V is the volume, in mL, of Injection taken, and the parenthetic expressions are the differences in the absorbances of the two solutions at the wavelengths indicated by the subscripts, for the assay solution (U) and the Standard solution (S), respectively.

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

Topic/Question	Contact	Expert Committee
TRIFLUOPERAZINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

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