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Trifluoperazine Oral Solution

» Trifluoperazine Oral Solution contains an amount of trifluoperazine hydrochloride ($C_{21}H_{24}F_3N_3S \cdot 2HCl$) equivalent to not less than 93.0 percent and not more than 107.0 percent of the labeled amount of trifluoperazine ($C_{21}H_{24}F_3N_3S$).

Packaging and storage—Preserve in tight, light-resistant containers.

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—

Change to read:

A: ▲*Spectroscopic Identification Tests ⟨197⟩, Ultraviolet-Visible Spectroscopy: 197U*▲ (CN 1-May-2020) —

Solution: Prepared as directed in the *Assay*.

B: Mix 1 mL of Oral Solution with 5 mL of methanol: a 5-µL portion of this solution meets the requirements of *Identification* test *D* under *Trifluoperazine Hydrochloride.*

pH ⟨791⟩: between 2.0 and 3.2.

Assay—[Note—Use low-actinic glassware.] Transfer an accurately measured volume of Oral Solution, equivalent to about 50 mg of trifluoperazine, to a 250-mL separator with the aid of about 100 mL of water. Add 10 mL of sodium hydroxide solution (1 in 10), and extract with three 50-mL portions of cyclohexane. Wash the combined cyclohexane extracts with about 20 mL of water, and discard the water washing. Extract the combined cyclohexane extracts with four 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 10.0 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 wavelength of maximum absorbance 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 Oral Solution taken by the formula:

$$(407.51/480.43)(5C/V)(A_{255} - A_{278})_U/(A_{255} - A_{278})_S$$

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 Oral Solution 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 ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

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