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Trifluoperazine Hydrochloride Tablets

» Trifluoperazine Hydrochloride Tablets contain 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 well-closed, 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—

A: The UV absorption spectrum of the solution employed for measurement of absorbance in the *Assay* exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Trifluoperazine Hydrochloride RS, concomitantly measured.

B: Triturate a portion of powdered Tablets, equivalent to about 10 mg of trifluoperazine, with 10 mL of methanol, and centrifuge. A 5-µL portion of this solution responds to *Identification* test *D* under *Trifluoperazine Hydrochloride.*

Dissolution ⟨711⟩—

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of trifluoperazine ($C_{21}H_{24}F_3N_3S$) dissolved from UV absorbances at the wavelength of maximum absorbance at about 255 nm (determine the analytical value to be used for the absorbance at 255 nm by subtracting the absorbance at 278 nm from the observed maximum absorbance at 255 nm), using filtered portions of the solution under test, suitably diluted with 0.1 N hydrochloric acid, in comparison with a Standard solution having a known concentration of USP Trifluoperazine Hydrochloride RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{21}H_{24}F_3N_3S$ is dissolved in 30 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Content Uniformity.*

Change to read:

Assay—

Mobile phase—To 2.9 g of *dl*-10-camphorsulfonic acid, add 200 mL of water and stir until solution is complete. Adjust with 1 N sodium hydroxide to a pH of 3.0, dilute with methanol to 1000 mL, mix, and filter through a 0.45-µm membrane filter.

Standard preparation—Dissolve an accurately weighed quantity of USP Trifluoperazine Hydrochloride RS in methanol to obtain a solution having a known concentration of about 12 µg of trifluoperazine hydrochloride per mL (10 µg of trifluoperazine per mL).

Assay preparation—Weigh and finely powder not less than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 20 mg of trifluoperazine, add to a 100-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with methanol to volume, and mix. Filter the solution through a 0.45-µm filter.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 262-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 2.0%, and the tailing factor for the trifluoperazine peak is not more than 2.0.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{21}H_{24}F_3N_3S$, in the portion of Tablets taken by the formula:

$$▲2000▲_{\text{(ERR 1-Oct-2019)}}\,(407.51/480.43)C(r_U/r_S)$$

in which 407.51 and 480.43 are the molecular weights of trifluoperazine and trifluoperazine hydrochloride, respectively, *C* is the concentration,

in mg per mL, of USP Trifluoperazine Hydrochloride RS in the *Standard preparation*, and r_U and r_S are the peak responses obtained 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
TRIFLUOPERAZINE HYDROCHLORIDE TABLETS	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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