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Triflupromazine Hydrochloride Tablets

» Triflupromazine Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{18}H_{19}F_3N_2S \cdot HCl$.

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

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: Triturate a portion of powdered Tablets, equivalent to about 50 mg of triflupromazine hydrochloride, with 5 mL of methanol, and centrifuge. A 10-µL portion of the supernatant meets the requirements of *Identification* test *C* under *Triflupromazine Hydrochloride*.

B: The solution prepared from the Tablets for measurement of absorbance in the *Assay* exhibits an absorbance maximum at 255 ± 2 nm.

Dissolution ⟨711⟩—

Medium: 0.01 N hydrochloric acid; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{18}H_{19}F_3N_2S \cdot HCl$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 305 nm on filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Triflupromazine Hydrochloride RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{18}H_{19}F_3N_2S \cdot HCl$ is dissolved in 45 minutes.

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

Assay—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 20 mg of triflupromazine hydrochloride, to a separator, add 10 mL of 0.1 N hydrochloric acid and 20 mL of water, and mix. Add 6 N ammonium hydroxide to render the mixture alkaline to litmus, add 1 mL in excess, and extract with five 50-mL portions of chloroform, passing each extract through anhydrous sodium sulfate into a 250-mL volumetric flask. Dilute with chloroform to volume, and mix. Evaporate 10.0 mL of this solution under reduced pressure to dryness, and dissolve the residue in 0.1 N hydrochloric acid to make 100.0 mL. Concomitantly determine the absorbances of this solution and of a Standard solution of USP Triflupromazine Hydrochloride RS in the same medium having a known concentration of about 8 µg per mL in 1-cm cells 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 $C_{18}H_{19}F_3N_2S \cdot HCl$ in the portion of Tablets taken by the formula:

$$2.5C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Triflupromazine Hydrochloride RS in the Standard solution, and A_U and A_S are the absorbances of the solution from the Tablets and the Standard solution, respectively.

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

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

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