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Triflupromazine Hydrochloride

$C_{18}H_{19}F_3N_2S \cdot HCl$ 388.88

10*H*-Phenothiazine-10-propanamine, *N*,*N*-dimethyl-2-(trifluoromethyl)-, monohydrochloride.

10-[3-(Dimethylamino)propyl]-2-(trifluoromethyl)phenothiazine monohydrochloride CAS RN®: 1098-60-8; UNII: 9E75N4A5HM.

» Triflupromazine Hydrochloride contains not less than 97.0 percent and not more than 103.0 percent of $C_{18}H_{19}F_3N_2S \cdot HCl$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed, light-resistant glass 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 by using low-actinic glassware.]

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

Change to read:

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

Solution: 10 µg per mL.

Medium: 0.5 N sulfuric acid.

Absorptivities at 255 nm, calculated on the dried basis, do not differ by more than 3.0%.

C: Prepare a solution of Triflupromazine Hydrochloride in methanol containing 10 mg per mL. Apply 10 µL each of this solution and a Standard solution of USP Triflupromazine Hydrochloride RS in methanol containing 10 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of *n*-propyl alcohol, water, and ammonium hydroxide (88:11:1) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by spraying lightly with dilute methanolic sulfuric acid (4 in 10) and then heating for 15 minutes: the R_F value and color (pink-orange) of the principal spot obtained from the test solution correspond to that obtained from the Standard solution.

Loss on drying ⟨731⟩—Dry it at 100° for 2 hours: it loses not more than 0.5% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Ordinary impurities ⟨466⟩—

Test solution: acetone.

Standard solution: acetone.

Eluant: a mixture of chloroform and methanol (4:1).

Visualization: 1.

Assay—Dissolve about 800 mg of Triflupromazine Hydrochloride, accurately weighed, in 100 mL of glacial acetic acid. Add 10 mL of mercuric acetate TS and 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a blue endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 38.89 mg of $C_{18}H_{19}F_3N_2S \cdot HCl$.

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

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