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Triprolidine Hydrochloride Tablets

» Triprolidine Hydrochloride Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$.

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

USP Reference standards ⟨11⟩—
USP Triprolidine Hydrochloride RS

Identification—

A: Weigh and finely powder not less than 20 Tablets. Transfer a portion of the powder, equivalent to about 20 mg of triprolidine hydrochloride, to a glass-stoppered test tube, add 20 mL of water, and shake for 3 minutes. Add 2 mL of 1 N sodium hydroxide, mix, then add 3 mL of cyclohexane, shake for 3 minutes, and centrifuge for 5 minutes: the IR absorption spectrum of the clear supernatant so obtained exhibits maxima only at the same wavelengths as that of a similar preparation of USP Triprolidine Hydrochloride RS.

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation* as obtained in the *Assay*.

Dissolution ⟨711⟩—

Medium: pH 4.0 ± 0.05 acetate buffer, prepared by mixing 4.9 g of glacial acetic acid and 2.45 g of sodium acetate trihydrate with water to obtain 1000 mL of solution; 500 mL.

Apparatus 1: 50 rpm.

Time: 30 minutes.

Procedure—Determine the amount of $C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 277 nm of filtered portions of the solution under test, in comparison with a Standard solution having a known concentration of USP Triprolidine Hydrochloride RS in the same medium.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$ is dissolved in 30 minutes.

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

Procedure for content uniformity—Transfer 1 Tablet to a 100-mL volumetric flask, add 70 mL of water, and sonicate, swirling the flask intermittently, until the tablet is dissolved. Dilute with water to volume, mix, and filter, discarding the first 50 mL of the filtrate. Dilute a portion of the filtrate quantitatively and stepwise with 0.1 N sulfuric acid to obtain a solution having a concentration of about 1.25 µg of triprolidine hydrochloride per mL. Concomitantly determine the fluorescence intensities of this solution and a similarly prepared Standard solution having a known concentration of about 1.25 µg of USP Triprolidine Hydrochloride RS per mL, at the excitation wavelength of 300 nm with a slit width of 2 mm, and an emission wavelength of 460 nm with a slit width of 2 mm, with a suitable spectrophotometer, using 0.1 N sulfuric acid as the blank. Calculate the quantity, in mg, of $C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$ in the Tablet taken by the formula:

$$(332.88/314.86)(TC/D)(I_U/I_S)$$

in which 332.88 and 314.86 are the molecular weights of the monohydrate and anhydrous forms of triprolidine hydrochloride, respectively; T is the labeled quantity, in mg, of triprolidine hydrochloride in the Tablet; C is the concentration, in µg per mL, of USP Triprolidine Hydrochloride RS in the Standard solution; D is the concentration, in µg per mL, of triprolidine hydrochloride in the solution from the Tablet, on the basis of the labeled quantity per Tablet and the extent of dilution, and I_U and I_S are the fluorescence intensities of the solution from the Tablet and the Standard solution, respectively.

Assay—

Mobile phase and *Standard preparation*—Prepare as directed in the *Assay* under *Triprolidine Hydrochlorides Oral Solution*.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 5.0 mg of triprolidine hydrochloride, to a 100-mL volumetric flask. Add about 10 mL of 0.01 N hydrochloric acid, and sonicate for 10 minutes. Cool to room temperature. Dilute with 0.01 N hydrochloric acid to volume, mix, and filter.

Chromatographic system and *Procedure*—Proceed as directed in the *Assay* under *Triprolidine Hydrochlorides Oral Solution,* except to calculate the quantity, in mg, of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) in the portion of Tablets taken by the formula:

$$(332.88/314.86)(100C)(r_U/r_S)$$

in which 332.88 and 314.86 are the molecular weights of triprolidine hydrochloride monohydrate and anhydrous triprolidine hydrochloride, respectively; C is the concentration, in mg per mL, calculated on the anhydrous basis, of USP Triprolidine 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
TRIPROLIDINE HYDROCHLORIDE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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