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Triprolidine and Pseudoephedrine Hydrochlorides Tablets

» Triprolidine and Pseudoephedrine Hydrochlorides Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

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

USP Reference standards ⟨11⟩—
USP Triprolidine Hydrochloride RS
USP Pseudoephedrine Hydrochloride RS

Identification—

A: The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those of the *Standard preparation* as obtained in the *Assay*.

B: Transfer 1 Tablet to a suitable glass-stoppered tube, add 10 mL of water, shake for 5 minutes, and allow the solids to settle. Prepare a Standard solution in water of USP Pseudoephedrine Hydrochloride RS and USP Triprolidine Hydrochloride RS having known concentrations of 6 mg per mL and 250 µg per mL, respectively. Separately apply 10-µL portions of the test solution and the Standard solution 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 butyl alcohol, glacial acetic acid, and water (8:2:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate, mark the solvent front, allow the solvent to evaporate, and examine the plate under short- and long-wavelength UV light: the R_F values of the principal spots obtained from the test solution correspond to those obtained from the Standard solution.

Dissolution, *Procedure for a Pooled Sample ⟨711⟩*—
Medium: water; 900 mL.
Apparatus 2: 50 rpm.
Time: 45 minutes.
Determine the amounts of pseudoephedrine hydrochloride and triprolidine hydrochloride dissolved using the following method.
Mobile phase and *Chromatographic system*—Proceed as directed in the *Assay* under *Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution*.
Procedure—Inject an accurately measured volume (about 200 µL) of a filtered portion of the solution under test into the chromatograph by means of a microsyringe or a sampling valve, record the chromatogram, and measure the responses for the major peaks. Calculate the quantities of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) and triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$) dissolved in comparison with a Standard solution having known concentrations of USP Pseudoephedrine Hydrochloride RS and USP Triprolidine Hydrochloride RS in the same medium and similarly chromatographed.
Tolerances—Not less than 75% *(Q)* of the labeled amounts of $C_{10}H_{15}NO \cdot HCl$ and $C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Content Uniformity* with respect to triprolidine hydrochloride and to pseudoephedrine hydrochloride.

Assay—
Mobile phase and *Standard preparation*—Prepare as directed in the *Assay* under *Triprolidine and Pseudoephedrine 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 120 mg of pseudoephedrine 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 (see *Chromatography ⟨621⟩*) and *Procedure*—Proceed as directed in the *Assay* under *Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution,* except to calculate the quantity, in mg, of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Tablets taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Pseudoephedrine Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the peak responses for pseudoephedrine hydrochloride obtained from the *Assay preparation* and the *Standard preparation*, respectively. 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 for triprolidine hydrochloride 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 AND PSEUDOEPHEDRINE HYDROCHLORIDES 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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