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# Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution

» Triprolidine and Pseudoephedrine Hydrochlorides Oral Solution contains 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 in the chromatogram of the *Standard preparation,* as obtained in the *Assay.*

**B:** Transfer 10 mL of Oral Solution to a suitable glass-stoppered tube, add 10 mL of ether and 2 mL of 1 N sodium hydroxide, shake for 5 minutes, and allow the layers to separate. The ether layer is the test solution. 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-wavelength 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.

**Assay**—

*Mobile phase*—Prepare a filtered and degassed mixture of alcohol and 0.40% ammonium acetate solution (17:3). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

*Standard preparation*—Dissolve accurately weighed quantities of USP Pseudoephedrine Hydrochloride RS and USP Triprolidine Hydrochloride RS in 0.01 N hydrochloric acid, and dilute quantitatively and stepwise with 0.01 N hydrochloric acid to obtain a solution having known concentrations of about 1.2 mg of USP Pseudoephedrine Hydrochloride RS per mL and about 0.05 mg of anhydrous USP Triprolidine Hydrochloride RS per mL, and filter.

*Assay preparation*—Transfer an accurately measured volume of Oral Solution, equivalent to about 60 mg of pseudoephedrine hydrochloride, to a 50-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix.

*Chromatographic system* (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4.6-mm × 25-cm column that contains packing L3. 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 is not more than 2.0%; and the resolution factor between triprolidine and pseudoephedrine is not less than 2.0. The tailing factor for the triprolidine peak is not more than 2.0, and the pseudoephedrine peak is not more than 2.0.

*Procedure*—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 0.68 for pseudoephedrine hydrochloride and 1.0 for triprolidine hydrochloride. Calculate the quantity, in mg, of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Oral Solution taken by the formula:

$$50C(r_U/r_S)$$

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 Oral Solution taken by the formula:

$$(332.88/314.86)(50C)(r_U/r_S)$$

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 |
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| TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES ORAL SOLUTION | Documentary Standards Support | SM52020 Small Molecules 5 |
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**Chromatographic Database Information:** Chromatographic Database

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