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Triprolidine Hydrochloride Oral Solution

» Triprolidine Hydrochloride Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of triprolidine hydrochloride ($C_{19}H_{22}N_2 \cdot HCl \cdot H_2O$).

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

USP Reference standards ⟨11⟩—
USP Triprolidine Hydrochloride RS

Identification—

A: Transfer a volume of Oral Solution, equivalent to about 12 mg of triprolidine hydrochloride, to a 125-mL separator, add 25 mL of water, then add 4 mL of sodium hydroxide solution (1 in 2), and mix. Add 10 mL of cyclohexane, shake, allow the phases to separate completely, and discard the aqueous layer. Transfer 8 mL of the cyclohexane solution to a glass-stoppered, 25-mL conical flask, evaporate on a steam bath with the aid of a current of air to dryness, and continue to heat the flask for about 1 minute after the solvent has completely evaporated. Cool, add 2 mL of cyclohexane, and mix: the IR absorption spectrum of the cyclohexane solution 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.*

pH ⟨791⟩: between 5.6 and 6.6.

Alcohol Determination, *Method II* ⟨611⟩: between 3.0% and 5.0% of C_2H_5OH.

Assay—

Mobile phase—Prepare a suitable degassed and filtered mixture of alcohol and ammonium acetate solution (1 in 250) (17:3).

Standard preparation—Dissolve an accurately weighed quantity of 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 a known concentration of about 0.05 mg of anhydrous USP Triprolidine Hydrochloride RS per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 2.5 mg of triprolidine 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 4.2-mm × 25-cm column that contains packing L3. The flow rate is about 1.5 mL per minute. Chromatograph five 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 tailing factor is not more than 1.5.

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. 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 obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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