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Tetracaine Hydrochloride Ophthalmic Solution

» Tetracaine Hydrochloride Ophthalmic Solution is a sterile, aqueous solution of Tetracaine Hydrochloride. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{15}H_{24}N_2O_2 \cdot HCl$. It may contain suitable antimicrobial and thickening agents.

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

Labeling—Label it to indicate that the Ophthalmic Solution is not to be used if it contains crystals, or if it is cloudy or discolored.

USP Reference standards ⟨11⟩—

USP Tetracaine Hydrochloride RS

Identification—Add 5 mL of Ophthalmic Solution to 5 mL of water in a test tube, then add 1 mL of potassium thiocyanate solution (1 in 4): a crystalline precipitate is formed. Recrystallize the precipitate from water, and dry at 80° for 2 hours: the crystals so obtained melt between 130° and 132°.

Sterility Tests ⟨71⟩: meets the requirements.

pH ⟨791⟩: between 3.7 and 6.0.

Assay—

Mobile phase—Prepare 0.01 *M* of dibasic ammonium phosphate in water, and adjust with phosphoric acid to a pH of 3.0. Prepare a filtered and degassed mixture of this solution and acetonitrile (70:30). Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve an accurately weighed quantity of USP Tetracaine Hydrochloride RS in water to obtain a solution having a known concentration of about 0.1 mg per mL.

Assay preparation—Transfer an accurately measured volume of Ophthalmic Solution, equivalent to about 10 mg of tetracaine hydrochloride, to a 100-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 280-nm detector and a 4.6-mm × 25-cm column containing packing L10. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency is not less than 500 theoretical plates; the tailing factor for the analyte peak is not more than 2.0; and the relative standard deviation for replicate injections 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. Calculate the quantity, in mg, of $C_{15}H_{24}N_2O_2 \cdot HCl$ in each mL of the Ophthalmic Solution taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Tetracaine Hydrochloride RS in the *Standard preparation; V* is the volume, in mL, of Ophthalmic Solution taken; and r_U and r_S are the tetracaine 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
TETRACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION	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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