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Homatropine Hydrobromide Ophthalmic Solution

» Homatropine Hydrobromide Ophthalmic Solution is a sterile, buffered, aqueous solution of Homatropine Hydrobromide. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{16}H_{21}NO_3 \cdot HBr$. It may contain suitable antimicrobial agents.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
USP Homatropine Hydrobromide RS

Identification—

A: Proceed with Ophthalmic Solution as directed under *Identification—Organic Nitrogenous Bases ⟨181⟩*. The specified results are obtained.

B: It responds to the tests for *Bromide ⟨191⟩*.

Sterility Tests ⟨71⟩: meets the requirements.

pH ⟨791⟩: between 2.5 and 5.0.

Assay—

Standard preparation—Accurately weigh about 50 mg of USP Homatropine Hydrobromide RS, dissolve in water, and dilute with water in a volumetric flask to 100 mL. Dilute 10.0 mL of this solution with water to 50.0 mL to obtain a solution having a known concentration of about 100 µg per mL. Prepare this solution fresh.

Assay preparation—Transfer a portion of Ophthalmic Solution, equivalent to 50 mg of homatropine hydrobromide, to a 100-mL volumetric flask, and dilute with water to volume. Dilute 10.0 mL of this solution with water to 50.0 mL.

Procedure—Transfer duplicate 2-mL portions of the *Standard preparation* and of the *Assay preparation* to separate glass-stoppered, 40-mL centrifuge tubes. To one set of two tubes add 3 mL of water and 1 mL of sodium hydroxide solution (1 in 100). Heat these tubes in a boiling water bath for 20 minutes, and allow to cool to room temperature. To the remaining set of tubes, which serve as blanks for the *Standard preparation* and the *Assay preparation*, respectively, add 4 mL of water. To each tube, add 2 mL of approximately 0.2 M ceric sulfate in diluted sulfuric acid (prepared by dissolving 12.6 g of ceric ammonium sulfate in 50 mL of water and 3 mL of sulfuric acid, and diluting with water to 100 mL) and 20.0 mL of isooctane. Shake by mechanical means for 15 minutes, allow the layers to separate, and remove the isooctane from each tube. Concomitantly determine the absorbances of the isooctane solutions from the hydrolyzed aliquots in 1-cm cells at the wavelength of maximum absorbance at about 242 nm, with a suitable spectrophotometer, against the respective blanks. Calculate the quantity, in mg, of $C_{16}H_{21}NO_3 \cdot HBr$ in the portion of Ophthalmic Solution taken by the formula:

$$0.5C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Homatropine Hydrobromide RS in the *Standard preparation*; and A_U and A_S are the absorbances of the solutions 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
HOMATROPINE HYDROBROMIDE OPHTHALMIC SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3

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