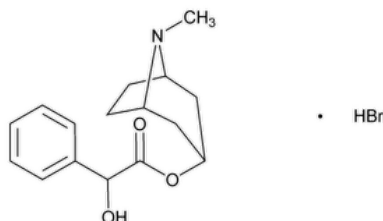


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Change to read:

Homatropine Hydrobromide



$C_{16}H_{21}NO_3 \cdot HBr$ Δ 356.26 Δ (ERR 1-Jul-2022)

Benzeneacetic acid, α -hydroxy-, 8-methyl-8-azabicyclo[3.2.1]octan-3-yl ester, hydrobromide, *endo*-($\pm$)-.

Δ (1*R*,3*r*,5*S*)-8-Methyl-8-azabicyclo[3.2.1]octan-3-yl 2-hydroxy-2-phenylacetate hydrobromide Δ (ERR 1-Jul-2022) CAS RN[®]: 51-56-9; UNII: BEW7469QZ0.

» Homatropine Hydrobromide contains not less than 98.0 percent and not more than 102.0 percent of $C_{16}H_{21}NO_3 \cdot HBr$, calculated on the dried basis.

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

USP REFERENCE STANDARDS (11)—

[USP Homatropine Hydrobromide RS](#)
[USP Scopolamine Hydrobromide RS](#)

Identification—

A: [Spectroscopic Identification Tests \(197\)](#), [Infrared Spectroscopy: 197K](#).

B: It responds to the tests for [Bromide \(191\)](#).

pH (791): between 5.7 and 7.0, in a solution (1 in 50).

LOSS ON DRYING (731)—Dry it at 105° for 2 hours; it loses not more than 1.5% of its weight.

RESIDUE ON IGNITION (281): not more than 0.25%.

Limit of tropine—

Adsorbent: 0.2-mm layer of chromatographic silica gel mixture.

Diluent—Prepare a mixture of methanol and water (9:1).

Test solution—Transfer about 0.2 g of Homatropine Hydrobromide to a 5-mL volumetric flask, dissolve in and dilute with *Diluent* to volume, and mix.

Standard solution—Dilute 0.5 mL of the *Test solution* with *Diluent* to 100.0 mL.

Tropine reference solution—Prepare a solution of tropine having a concentration of about 0.4 mg per mL in *Diluent*.

Application volume: 1 μ L.

Developing solvent system: a mixture of ethyl acetate, anhydrous formic acid, and water (67: 16.5: 16.5).

Procedure—Proceed as directed for *Thin-Layer Chromatography* under [Chromatography \(621\)](#), applying the *Test solution*, the *Standard solution*, and the *Tropine reference solution*. Spray the plate with Dragendorff's reagent, followed by hydrogen peroxide TS, and immediately cover with a glass plate of the same size. Examine the plate no later than 5 to 10 minutes after spraying. In the chromatogram obtained from the *Test solution*, identify the spot corresponding to the principal spot in the chromatogram of the *Tropine reference solution*: this spot is not more intense than the spot obtained from the *Standard solution*: not more than 0.5% of tropine is found.

Chromatographic purity—

Buffer solution, Mobile phase, System suitability solution, and Chromatographic system—Proceed as directed in the Assay.

Standard solution—Use the *Standard preparation*, prepared as directed in the Assay.

Test solution—Use the *Assay preparation*, prepared as directed in the Assay.

Procedure—Separately inject a volume (about 7 μ L) of the *Test solution* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Continue the elution for 2.2 times the retention time of the homatropine peak. Disregard the peak for the

bromide ion, which appears close to the solvent peak. Calculate the percentage of each impurity in the portion of Homatropine Hydrobromide taken by the formula:

$$100(r_i/r_s)$$

in which r_i and r_s are the peak response for each impurity and the sum of all peak responses, respectively, obtained from the *Test solution*. In addition to not exceeding the limits for each impurity in [Table 1](#), not more than 0.1% of any other individual impurity is found; and not more than 1.0% of total impurities is found.

Table 1

Impurity	Relative Retention Time	Limit (%)
Mandelic acid	0.3	0.1
Dehydrohomatropine	0.9	0.5
Scopolamine	1.1	0.1
Atropine	1.9	0.1

Assay—

Buffer solution—Dissolve 6.8 g of monobasic potassium phosphate and 7.0 g of sodium 1-heptanesulfonate monohydrate in 1000 mL of water, adjust with 3 M phosphoric acid to a pH of 2.7, and mix.

Mobile phase—Prepare a filtered and degassed mixture of *Buffer solution* and methanol (67:33).

Standard preparation—Dissolve an accurately weighed quantity of [USP Homatropine Hydrobromide RS](#) in *Mobile phase* to obtain a solution having a concentration of about 2 mg per mL.

System suitability solution—Prepare a solution of [USP Scopolamine Hydrobromide RS](#) having a concentration of about 0.1 mg per mL. Transfer 10 mL of this solution to a 100-mL volumetric flask, add 0.5 mL of the *Standard preparation*, and dilute with *Mobile phase* to volume.

Assay preparation—Transfer about 100 mg of Homatropine Hydrobromide, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see [CHROMATOGRAPHY \(621\)](#))—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 10-cm column that contains 3-μm packing L1. The flow rate is about 1.5 mL per minute. The column temperature is maintained at 40°.

Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 1.0%. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the resolution between homatropine and scopolamine peaks is not less than 1.5.

Procedure—Separately inject equal volumes (about 7 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 $C_{16}H_{21}NO_3 \cdot HBr$ in the portion of Homatropine Hydrobromide taken by the formula:

$$50C(r_i/r_s)$$

in which C is the concentration, in mg per mL, of [USP Homatropine Hydrobromide RS](#) in the *Standard preparation*; and r_i and r_s are the 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
HOMATROPINE HYDROBROMIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)