

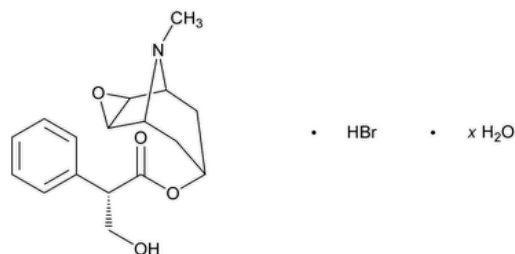
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Scopolamine Hydrobromide

Change to read:

▲



▲ (USP 1-Dec-2021)

 $C_{17}H_{21}NO_4 \cdot HBr \cdot \Delta x H_2O$ ▲ (USP 1-Dec-2021)

Benzeneacetic acid, α -(hydroxymethyl)-, 9-methyl-3-oxa-9-azatricyclo[3.3.1.0.^{2,4}]non-7-yl ester, hydrobromide, ▲hydrate, ▲ (USP 1-Dec-2021) [7(S)-(1 α ,2 β ,4 β ,5 α ,7 β)];

6 β ,7 β -Epoxy-1 α H,5 α H-tropan-3 α -ol (-)-tropate (ester) hydrobromide ▲hydrate;

(1R,2R,4S,5S,7s)-9-Methyl-3-oxa-9-azatricyclo[3.3.1.0.^{2,4}]nonan-7-yl (S)-3-hydroxy-2-phenylpropanoate hydrobromide hydrate ▲ (USP 1-Dec-2021)

Anhydrous 384.27 CAS RN[®]: 114-49-8; UNII: R3K67DRL3J.

DEFINITION

Scopolamine Hydrobromide contains NLT 98.0% and NMT 102.0% of scopolamine hydrobromide ($C_{17}H_{21}NO_4 \cdot HBr$), calculated on the anhydrous basis.

[CAUTION—Handle scopolamine hydrobromide with exceptional care, because it is highly potent.]

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

▲ **Sample:** ▲ (USP 1-Dec-2021) Dissolve 3 mg in 1 mL of alcohol, and evaporate the solution on a steam bath to dryness. Dissolve the residue in 0.5 mL of [chloroform](#), add 200 mg of [potassium bromide](#) previously dried at 105° for 30 min, and stir frequently for 5 min. Allow the chloroform to evaporate to dryness, and stir frequently to obtain a flowing powder residue. Dry the residue ▲ as directed in the test for *Water Determination*, ▲ (USP 1-Dec-2021) and then immediately compress the residue to a disk.

▲ **Standard solution:** Proceed as directed in the *Sample* using [USP Scopolamine Hydrobromide RS](#), ▲ (USP 1-Dec-2021)

Acceptance criteria: Meets the requirements

- **B.**

Sample solution: 50 mg/mL of Scopolamine Hydrobromide in [water](#)

Analysis: To 1 mL of the *Sample solution* add a few drops of [chlorine TS](#), and shake the mixture with 1 mL of [chloroform](#).

Acceptance criteria: A brownish color forms in the chloroform layer.

- **C.** The retention time of the scopolamine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **PROCEDURE**

Buffer solution: 7.0 g/L of monobasic potassium phosphate in [water](#). Adjust with [0.05 M phosphoric acid](#) to a pH of 3.3.

Solution A: Dissolve 3.5 g of [sodium dodecyl sulfate](#) in 606 mL of *Buffer solution*. Add 320 mL of [acetonitrile](#) and mix

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
2.0	95	5
20.0	70	30
20.1	95	5
25.0	95	5

Standard solution: 0.2 mg/mL of [USP Scopolamine Hydrobromide RS](#) in *Solution A*

Sample solution: 0.2 mg/mL of Scopolamine Hydrobromide in *Solution A*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 10-cm; 3-μm packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of scopolamine hydrobromide ($C_{17}H_{21}NO_4 \cdot HBr$) in the portion of Scopolamine Hydrobromide taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of scopolamine from the *Sample solution*

r_S = peak response of scopolamine from the *Standard solution*

C_S = concentration of [USP Scopolamine Hydrobromide RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Scopolamine Hydrobromide in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#)

Sample: 1 g

Acceptance criteria: NMT 0.1%

• **ORGANIC IMPURITIES**

Buffer solution, Solution A, Solution B, Mobile phase, and Chromatographic system: Proceed as directed in the Assay.

System suitability solution: 0.2 mg/mL of [USP Scopolamine Hydrobromide RS](#) and 0.001 mg/mL of [USP Norscopolamine RS](#) in *Solution A*

Standard solution: 0.002 mg/mL of [USP Scopolamine Hydrobromide RS](#) in *Solution A*

Sample solution: 2.0 mg/mL of Scopolamine Hydrobromide in *Solution A*

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements