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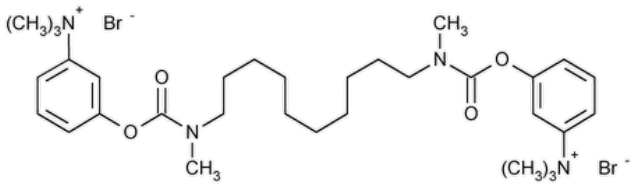
Demecarium Bromide



$C_{32}H_{52}Br_2N_4O_4$ 716.59

Benzenaminium, 3,3'-[1,10-decanediylbis[(methylimino)carbonyloxy]]bis[*N*,*N*,*N*-trimethyl]-, dibromide.

(*m*-Hydroxyphenyl)trimethylammonium bromide decame thylenebis[methylcarbamate] (2:1) CAS RN®: 56-94-0; UNII: 61D5V4OKTP.

» Demecarium Bromide contains not less than 95.0 percent and not more than 100.5 percent of $C_{32}H_{52}Br_2N_4O_4$, calculated on the anhydrous basis.

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

USP Reference standards ⟨11⟩—

USP Demecarium Bromide RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

B: Dissolve about 100 mg in 50 mL of 1 N sodium hydroxide, and reflux for 15 minutes. Cool, and add 3 mL of the refluxed solution to 25 mL of saturated sodium bicarbonate solution. Add, with mixing, 4 mL of *N*,*N*-dimethyl-*p*-phenylenediamine dihydrochloride solution (1.5 in 10,000) and 2 mL of sodium hypochlorite solution (1.5 in 20,000): a violet-blue color is produced.

C: Dissolve about 50 mg in 20 mL of water, add 10 mL of a 1 in 50 solution of ammonium reineckate in methanol, and allow to stand for 30 minutes with occasional swirling: a pink reineckate of demecarium forms, and it melts between 131° and 136°, with decomposition.

D: A solution of it responds to the tests for *Bromide* ⟨191⟩.

pH ⟨791⟩**:** between 5.0 and 7.0, in a solution (1 in 100).

Water Determination, *Method I* ⟨921⟩**:** not more than 2.0%.

Residue on ignition ⟨281⟩**:** not more than 0.1%.

Limit of *m*-trimethylammoniophenol bromide—

Control solution—Dissolve 100 mg of *m*-dimethylaminophenol in 10 mL of alcohol in a 1000-mL volumetric flask, dilute with water to volume, and mix. Pipet 1 mL of this solution into a 500-mL volumetric flask, dilute with water to volume, and mix.

Test solution—Transfer 100 mg of Demecarium Bromide to a 100-mL volumetric flask, add water to volume, and mix.

Procedure—Pipet 25 mL of the *Test solution* into a glass-stoppered, 50-mL centrifuge tube, and pipet 25 mL of the *Control solution* into a second, similar tube. To each tube add 3 mL of pH 7.0 phosphate buffer (see under *Solutions* in the section *Reagents, Indicators, and Solutions*), 1 mL of *N*,*N*-dimethyl-*p*-phenylenediamine dihydrochloride solution (1.5 in 10,000), 5 mL of isobutyl alcohol, and 1 mL of sodium hypochlorite solution (1.5 in 20,000). Insert the stoppers in the tubes, shake the mixtures for 5 minutes, and centrifuge: any blue color produced in the upper layer obtained from the *Test solution* is not more intense than that obtained from the *Control solution*.

Assay—Dissolve about 0.8 g of Demecarium Bromide, accurately weighed, in a mixture of 75 mL of glacial acetic acid and 15 mL of mercuric acetate TS, warming slightly, if necessary, to effect solution. Add 2 drops of crystal violet TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 35.83 mg of $C_{32}H_{52}Br_2N_4O_4$.

Topic/Question	Contact	Expert Committee
DEMECARIUM BROMIDE	Documentary Standards Support	SM42020 Small Molecules 4

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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