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Brompheniramine Maleate Oral Solution

» Brompheniramine Maleate Oral Solution contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of brompheniramine maleate ($C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$).

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

USP Reference standards ⟨11⟩—
USP Brompheniramine Maleate RS

Identification—Transfer a volume of Oral Solution, equivalent to about 50 mg of brompheniramine maleate, to a separator, render distinctly alkaline with 1 N sodium hydroxide, and extract with two 50-mL portions of chloroform, shaking gently to avoid emulsification. Wash the combined chloroform extracts with 10 mL of water, and discard the aqueous phase. Filter the combined chloroform extracts into a conical flask, and evaporate the solvent on a steam bath, with the aid of a current of air. To the residue add 25 mL of dilute hydrochloric acid (1 in 1200), and proceed as directed under *Identification—Organic Nitrogenous Bases* ⟨181⟩, beginning with "Transfer the liquid to a separator." The Oral Solution meets the requirements of the test.

pH ⟨791⟩: between 2.5 and 3.5.

Alcohol Determination, *Method I* ⟨611⟩: between 2.7% and 3.3% of C_2H_5OH.

Assay—Transfer an accurately measured volume of Oral Solution, equivalent to about 20 mg of brompheniramine maleate, to a separator, render distinctly alkaline with 1 N sodium hydroxide, and extract with ten 10-mL portions of chloroform, shaking gently to avoid emulsification. Wash the combined chloroform extracts with 10 mL of water, wash the latter with 20 mL of chloroform, and discard the aqueous phase. Quantitatively filter the combined chloroform extracts and washings into a conical flask, and evaporate the solvent on a steam bath, with the aid of a current of air. To the residue add 25 mL of glacial acetic acid and 5 mL of acetic anhydride, agitate, and allow to stand for about 15 minutes. Add 1 drop of crystal violet TS, and titrate with 0.01 N perchloric acid VS to a blue-green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.01 N perchloric acid is equivalent to 2.177 mg of brompheniramine maleate ($C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$).

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BROMPHENIRAMINE MALEATE ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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