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Brompheniramine Maleate Tablets

» Brompheniramine Maleate Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Brompheniramine Maleate RS

Identification—Tablets meet the requirements under *Identification—Organic Nitrogenous Bases ⟨181⟩*.

Dissolution ⟨711⟩—

Medium: water; 500 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 264 nm on filtered portions of the solution under test, suitably diluted with 3 N hydrochloric acid, using 5-cm cuvettes, in comparison with a Standard solution having a known concentration of USP Brompheniramine Maleate RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Standard preparation—Dissolve an accurately weighed quantity of USP Brompheniramine Maleate RS in water, and dilute quantitatively with water to obtain a solution having a known concentration of about 160 µg per mL. Transfer 25.0 mL of this solution to a separator containing 25 mL of water, mix, and proceed as directed under *Assay preparation*, beginning with "adjust with sodium hydroxide solution (1 in 10) to a pH of 11." The concentration of USP Brompheniramine Maleate RS in the *Standard preparation* is about 20 µg per mL.

Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 4 mg of brompheniramine maleate, mix with 50 mL of water for 10 minutes, adjust with sodium hydroxide solution (1 in 10) to a pH of 11, and cool to room temperature. Extract the mixture with two 75-mL portions of solvent hexane, and combine the extracts in a second separator. Extract the solvent hexane solution with three 50-mL portions of dilute hydrochloric acid (1 in 120), combining the acid extracts in a 200-mL volumetric flask. Add dilute hydrochloric acid (1 in 120) to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Assay preparation* and the *Standard preparation,* in 1-cm cells at the wavelength of maximum absorbance at about 264 nm, with a suitable spectrophotometer, using dilute hydrochloric acid (1 in 120) as the blank. Calculate the quantity, in mg, of $C_{16}H_{19}Br\,N_2 \cdot C_4H_4O_4$ in the portion of Tablets taken by the formula:

$$0.2C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Brompheniramine Maleate RS in the *Standard preparation;* and A_U and A_S are the absorbances of 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
BROMPHENIRAMINE MALEATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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