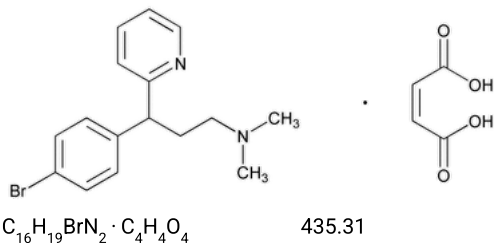


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Brompheniramine Maleate



2-Pyridinepropanamine, γ -(4-bromophenyl)-*N,N*-dimethyl-, ($\pm$), (*Z*)-2-butenedioate (1:1);
($\pm$)-2-*p*-Bromo- α -2-(dimethylamino)ethylbenzylpyridine maleate (1:1) CAS RN®: 980-71-2; UNII: IXA7C9ZN03.

DEFINITION
Brompheniramine Maleate, dried at 105° for 3 h, contains NLT 98.0% and NMT 102.0% of brompheniramine maleate ($C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$).

IDENTIFICATION

- A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)
- B.** The retention times of the maleic acid and brompheniramine peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the Assay.

ASSAY

- PROCEDURE**
Solution A: 5.44 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0 $\pm$ 0.1.
Solution B: Acetonitrile
Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
1	95	5
20	70	30
30	70	30
31	95	5
40	95	5

Diluent: Acetonitrile and *Solution A* (5:95)
System suitability stock solution: 0.02 mg/mL each of [USP Pheniramine Maleate RS](#), [USP Chlorpheniramine Maleate RS](#), and [USP Chlorpheniramine Related Compound B RS](#) in *Diluent*. Sonicate for 1 min.
System suitability solution: 0.5 mg/mL of [USP Brompheniramine Maleate RS](#) and 2 μ g/mL each of [USP Pheniramine Maleate RS](#), [USP Chlorpheniramine Maleate RS](#), and [USP Chlorpheniramine Related Compound B RS](#) in *Diluent*, prepared as follows. Transfer 5.0 mg of [USP Brompheniramine Maleate RS](#) to a 10-mL volumetric flask, add 5.0 mL of *Diluent*, and 1.0 mL of the *System suitability stock solution*, and dilute with *Diluent* to volume.
Standard solution: 0.5 mg/mL of [USP Brompheniramine Maleate RS](#) in *Diluent*. Sonicate for 1 min.
Sample solution: 0.5 mg/mL of Brompheniramine Maleate in *Diluent*. Sonicate for 1 min.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC**Detector:** UV 225 nm**Column:** 4.6-mm × 25-cm; 5-μm packing L1**Column temperature:** 30°**Flow rate:** 1 mL/min**Injection volume:** 10 μL**System suitability**

[NOTE—The relative retention times for maleic acid and brompheniramine are 0.18 and 1.0, respectively.]

Samples: *System suitability solution* and *Standard solution***Suitability requirements****Resolution:** NLT 1.5 between chlorpheniramine and brompheniramine; and NLT 2.0 between chlorpheniramine related compound B and pheniramine, *System suitability solution***Tailing factor:** NMT 2.0 for brompheniramine, *Standard solution***Relative standard deviation:** NMT 0.73%, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*Calculate the percentage of brompheniramine maleate ($C_{16}H_{19}BrN_2 \cdot C_4H_4O_4$) in the portion of Brompheniramine Maleate taken:

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

 r_U = peak response of brompheniramine from the *Sample solution* r_S = peak response of brompheniramine from the *Standard solution* C_S = concentration of [USP Brompheniramine Maleate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Brompheniramine Maleate in the *Sample solution* (mg/mL)**Acceptance criteria:** NLT 98.0%–NMT 102.0% on the previously dried basis**IMPURITIES**• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%• **ORGANIC IMPURITIES****Solution A, Solution B, Diluent, Mobile phase, System suitability solution, and Chromatographic system:** Proceed as directed in the Assay.**Standard solution:** 2.7 μg/mL of [USP Brompheniramine Maleate RS](#) in *Diluent*, equivalent to 2.0 μg/mL of brompheniramine. Sonicate 1 min.**Sensitivity solution:** 0.74 μg/mL of [USP Pheniramine Maleate RS](#) in *Diluent***Sample solution:** 0.5 mg/mL of Brompheniramine Maleate in *Diluent*. Sonicate for 1 min.**System suitability****Samples:** *System suitability solution*, *Standard solution*, and *Sensitivity solution***Suitability requirements****Resolution:** NLT 1.5 between chlorpheniramine and brompheniramine; and NLT 2.0 between chlorpheniramine related compound B and pheniramine, *System suitability solution***Signal-to-noise ratio:** NLT 10 for pheniramine, *Sensitivity solution***Relative standard deviation:** NMT 5.0% for brompheniramine, *Standard solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Brompheniramine Maleate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

 r_U = peak response of each impurity from the *Sample solution* r_S = peak response of brompheniramine from the *Standard solution* C_S = concentration of brompheniramine in the *Standard solution* (mg/mL) C_U = concentration of Brompheniramine Maleate in the *Sample solution* (mg/mL) F = relative response factor (see [Table 2](#))**Acceptance criteria:** See [Table 2](#). Disregard any peak having areas less than 0.05% of brompheniramine.**Table 2**