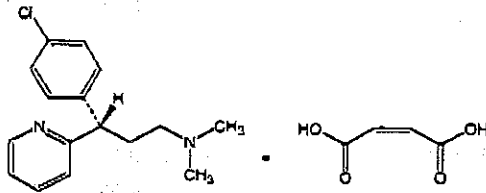


Dexchlorpheniramine Maleate



$C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ 390.86
2-Pyridinopropanamine, γ -(4-chlorophenyl)-*N,N*-dimethyl-, (*S*)-,
(*Z*)-2-butenedioate (1:1).
(+)-2-[*p*-Chloro- α -[2-(dimethylamino)ethyl]benzyl]pyridine maleate (1:1)
[2438-32-6].

>> Dexchlorpheniramine Maleate, dried at 65° for 4 hours, contains not less than 98.0 percent and not more than 100.5 percent of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$.

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

USP Reference standards <11>—*USP Dexchlorpheniramine Maleate RS*.

Identification—

A: *Infrared Absorption* <197K>.

B: *Ultraviolet Absorption* <197U>—

Solution: 40 μ g per mL.

Medium: water.

Melting range, Class I <741>: between 110° and 115°.

Specific rotation <781S>: between +39.5° and +43.0°.

Test solution: 50 mg per mL, in dimethylformamide.

pH <791>: between 4.0 and 5.0, in a solution (1 in 100).

Loss on drying <731>—Dry it at 65° for 4 hours: it loses not more than 0.5% of its weight.

Residue on ignition <281>: not more than 0.2%.

Related compounds—

Test solution—Dissolve about 200 mg of Dexchlorpheniramine Maleate in 5 mL of methylene chloride, and mix.

Chromatographic system (see *Chromatography* <621>)—The gas chromatograph is equipped with a flame-ionization detector and a 1.2-m \times 4-mm glass column containing 3% phase G3 on support S1AB. The column temperature is maintained at about 190°, and the injection port and detector temperatures are both maintained at about 250°. The carrier gas is dry helium, flowing at a rate adjusted to obtain a retention time of 4 to 5 minutes for the main peak. Chromatograph the *Test preparation*, record the chromatogram, and determine the peak area as directed under *Procedure*: the tailing factor for the dexchlorpheniramine maleate peak is not more than 1.8.

Procedure—Inject a volume (about 1 μ L) of the *Test solution* into the chromatograph. Record the chromatogram for a total time of not less than twice the retention time of the dexchlorpheniramine peak, and measure the areas of the peaks. The total relative area of all extraneous peaks (except that of the solvent peak and maleic acid, if observed) does not exceed 2.0%.

Organic volatile impurities, Method I <467>: meets the requirements.

(Official until July 1, 2008)

Assay—Dissolve about 400 mg of Dexchlorpheniramine Maleate, previously dried and accurately weighed, in 50 mL of glacial acetic acid, add 1 drop of crystal violet TS, and titrate with 0.1 N perchloric acid VS to a green endpoint. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 19.54 mg of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$.