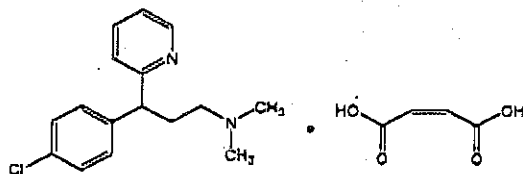


Chlorpheniramine Maleate



$C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ 390.86

2-Pyridinepropanamine, γ -(4-chlorophenyl)-*N,N*-dimethyl-, (*Z*)-2-butenedioate (1:1).
2-[*p*-Chloro- α -[2-(dimethylamino)ethyl]benzyl]pyridine maleate (1:1) [113-92-8].

>> Chlorpheniramine Maleate contains not less than 98.0 percent and not more than 100.5 percent of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$, calculated on the dried basis.

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

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

Identification, Infrared Absorption <197K>.

Melting range <741>: between 130° and 135°.

Loss on drying <731>—Dry it at 105° for 3 hours: it loses not more than 0.5% of its weight.

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

Related compounds—

Test preparation—Dissolve about 200 mg of Chlorpheniramine 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 for *Procedure*; the tailing factor for the chlorpheniramine maleate peak is not more than 1.8.

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

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

(Official until July 1, 2008)

Assay—Dissolve about 500 mg of Chlorpheniramine Maleate, accurately weighed, in 20 mL of glacial acetic acid. 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 19.54 mg of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$.