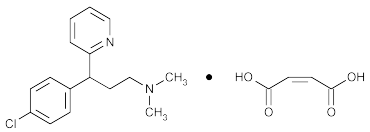
chloroxylenol (C_8H_9ClO) in the portion of Chloroxylenol taken by the formula:

$$100C(R_U / R_S)$$

in which *C* is the concentration, in mg per mL, of USP Chloroxylenol RS in the *Standard preparation;* and R_U and R_S are the ratios of the response of the chloroxylenol peak to that of the *p*-chlorophenol peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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 × 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 µL) 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 maleic acid, if obser ved) does not exceed 2.0%.

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 per chloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N per chloric acid is equivalent to 19.54 mg of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$.

Chlorpheniramine Maleate Extended-Release Capsules

» Chlorpheniramine Maleate Extended-Release Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$).

Packaging and storage—Preserve in tight containers.

Labeling—Label the Capsules to indicate the *Dissolution Test* with which the product complies.

USP Reference standards ⟨11⟩**—**
USP Chlorpheniramine Maleate RS

Identification—

A: The retention time of the chlorpheniramine peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

B: Transfer the contents of 1 Capsule to a 10-mL volumetric flask, add 5 mL of methanol, and insert the stopper into the flask. Sonicate this solution for 10 minutes, dilute with water to volume, mix, and filter. Apply separately 10 µL of this solution and 10 µL of a solution of USP Chlorpheniramine Maleate RS in a mixture of methanol and water (1:1) containing about 1.2 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of ethyl acetate, methanol, and ammonium hydroxide (100:5:5) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, allow the solvent to evaporate, and examine the plate under short-wavelength UV light: the R_F value of the principal spot obser ved in the chromatogram of the solution under test corresponds to that obtained from the Standard solution.

Dissolution ⟨711⟩**—**

TEST 1—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1.*

Medium: water; 500 mL.

Apparatus 1: 100 rpm.

Times: 1.5, 6.0, and 10.0 hours.

Procedure—Determine the amount of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ dissolved by employing the method set forth in the *Assay*, using a filtered portion of the solution under test in comparison with a Standard solution having a known concentration of USP Chlorpheniramine Maleate RS in the same medium.

Tolerances—The percentages of the labeled amount of $C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ dissolved at the times specified conform to *Acceptance Table 2.*

Time (hours)	Amount dissolved
1.5	between 15% and 40%
6.0	between 50% and 80%
10.0	not less than 70%

TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2.* Proceed as directed for *Procedure* for *Method B* under *Apparatus 1 and Apparatus 2, Delayed-Release Dosage Forms.*

Medium—Prepare as directed under *Method B,* except use 900 mL of media. Operate the apparatus for 1 hour in the *Acid Stage* and use the acceptance criteria given under *Tolerances.* Operate the apparatus for 6 hours in the *Buffer Stage*, except to use 900 mL of simulated intestinal fluid TS without enzyme, and use the acceptance criteria given under *Tolerances.*