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Chlorpheniramine Maleate Oral Solution

» Chlorpheniramine Maleate Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$).

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

USP Reference standards ⟨11⟩—
USP Chlorpheniramine Maleate RS

Identification—

A: Evaporate the remaining extract from the *Assay* on a steam bath to a small volume, then transfer it to a smaller, more suitable vessel, and evaporate just to the point where hexane vapors are no longer perceptible. Transfer the oily residue, with the aid of four 3-mL portions of dimethylformamide, to a suitable glass-stoppered graduated cylinder, dilute with dimethylformamide to 15.0 mL, and mix: the optical rotation of the solution so obtained, in a 100-mm tube, after correcting for the blank, is not more than +0.01° (*distinction from dexchlorpheniramine maleate*).

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)* —

Solution: the solution employed for measurement of absorbance in the *Assay*.

Alcohol Determination ⟨611⟩ (*if present*) ⟨611⟩: between 6.0% and 8.0% of C_2H_5OH.

Assay—Transfer 10 mL of Oral Solution, accurately measured, to a separator. Transfer about 40 mg of USP Chlorpheniramine Maleate RS, accurately weighed, to a 100-mL volumetric flask, dilute with water to volume, mix, and pipet 10 mL of this Standard solution into a separator similar to that containing the Oral Solution. Treat each solution as follows. Add 10 mL of sodium hydroxide solution (1 in 10), and extract with two 50-mL portions of solvent hexane. Combine the extracts in a second separator, wash with 10 mL of sodium hydroxide solution (1 in 250), and discard the washing. Extract the hexane solution with two 40-mL portions of dilute hydrochloric acid (1 in 100), collect the extracts in a 100-mL volumetric flask, add the same dilute acid to volume, and mix. Wash 50-mL portions of each solution, and of dilute hydrochloric acid (1 in 100), respectively, with three 30-mL portions of chloroform and then with 50 mL of solvent hexane, and discard the washings. Filter the acid phases through paper, discarding the first few mL of each filtrate, and determine the absorbances of the solutions obtained from the Oral Solution and the Standard solution in 1-cm cells at the wavelength of maximum absorbance at about 264 nm, with a suitable spectrophotometer, using the extracted acid as the blank. Calculate the quantity, in µg, of chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) in each mL of the Oral Solution taken by the formula:

$$C(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Chlorpheniramine Maleate RS in the Standard solution; and A_U and A_S are the absorbances of the solutions from the Oral Solution and the Standard solution, respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CHLORPHENIRAMINE MALEATE ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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