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Dexchlorpheniramine Maleate Oral Solution

» Dexchlorpheniramine Maleate Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dexchlorpheniramine 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 Dexchlorpheniramine 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 between +0.06° and +0.11° (*distinction from chlorpheniramine maleate*).

Change to read:

B: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Ultraviolet-Visible Spectroscopy: 197U*▲ *(CN 1-May-2020)*: *Assay preparation* compared to *Standard preparation* from *Assay*.

Alcohol Determination ⟨611⟩: between 5.0% and 7.0% of C_2H_5OH.

Assay—

Standard preparation—Transfer about 40 mg of USP Dexchlorpheniramine Maleate RS, accurately weighed, to a 100-mL volumetric flask, add water to volume, and mix. Transfer 10.0 mL of this solution to a separator, adjust with 1 N sodium hydroxide to a pH of 11, and cool. Extract with two 50-mL portions of solvent hexane, shaking each portion for 2 minutes before separating the phases, and combining the hexane extracts in a second separator. Extract the hexane solution with two 40-mL portions of dilute hydrochloric acid (1 in 120), combine the acid extracts in a 100-mL volumetric flask, add dilute hydrochloric acid (1 in 120) to volume, and mix. Filter the solution into a glass-stoppered conical flask, discarding the first few mL of the filtrate. The concentration of USP Dexchlorpheniramine Maleate RS in the *Standard preparation* is about 40 µg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 40 mg of dexchlorpheniramine maleate, to a 250-mL separator, using a pipet calibrated "to contain" the required volume. Rinse the pipet with small portions of water, add the rinsings to the separator, adjust with 1 N sodium hydroxide to a pH of 11, and cool. Extract with five 70-mL portions of solvent hexane, combine the hexane extracts in a 500-mL separator, and wash the hexane solution with two 10-mL portions of sodium hydroxide solution (1 in 250). Extract the combined alkaline washings with two 20-mL portions of solvent hexane, and add these extracts to the bulk of the alkali-washed hexane solution. Filter the hexane solution through a pledget of cotton that previously has been saturated with solvent hexane into a 500-mL volumetric flask, rinse the separator with portions of solvent hexane, pass the rinsings through the filter to add to volume, and mix. Transfer 50.0 mL of this solution to a separator (retain the remaining extract for *Identification* test *A*), and proceed as directed for *Standard preparation,* beginning with "Extract the hexane solution."

Procedure—Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* in 1-cm cells at the wavelength of maximum absorbance at about 264 nm, using dilute hydrochloric acid (1 in 120) as the blank. Calculate the quantity, in mg, of dexchlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) in each mL of the Oral Solution taken by the formula:

$$(C/V)(A_U/A_S)$$

in which C is the concentration, in µg per mL, of USP Dexchlorpheniramine Maleate RS in the *Standard preparation; V* is the volume, in mL, of Oral Solution taken; and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
DEXCHLORPHENIRAMINE MALEATE ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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