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Dexchlorpheniramine Maleate Tablets

DEFINITION

Dexchlorpheniramine Maleate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of dexchlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$).

IDENTIFICATION

- **A. Identification—Organic Nitrogenous Bases ⟨181⟩:** Meet the requirements
- **B.**

Analysis: Shake a quantity of finely powdered Tablets, equivalent to 150 mg of dexchlorpheniramine maleate, with 100 mL of 1 N acetic acid for 10 min, and filter through a sintered-glass funnel into a suitable vessel. Adjust the filtrate with sodium hydroxide solution (1 in 10) to a pH of 11, and extract the solution with six 100-mL portions of solvent hexane, filtering each hexane extract using suitable means to separate the hexane layer from the aqueous layer. Concentrate the combined extracts on a steam bath to a small volume, transfer 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, mix, and centrifuge if necessary.

Acceptance criteria: The optical rotation of the solution so obtained in a 100-mm tube after correcting for the blank is between +0.24° and +0.35° (distinction from chlorpheniramine maleate).

ASSAY

- **Procedure**

Diluent: Dilute hydrochloric acid (1 in 120)

Standard stock solution: 0.4 mg/mL of USP Dexchlorpheniramine Maleate RS in water

Standard solution: 40 µg/mL of USP Dexchlorpheniramine Maleate RS, prepared as follows. Transfer 10.0 mL of the *Standard stock 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 min before separating the phases, and combining the hexane extracts in a second separator. Extract the hexane solution with two 40-mL portions of *Diluent*, combine the *Diluent* extracts in a 100-mL volumetric flask, and add *Diluent* to volume. Filter the solution into a glass-stoppered conical flask, discarding the first few mL of the filtrate.

Sample solution: Nominally 40 µg/mL of dexchlorpheniramine maleate, prepared as follows. Transfer an equivalent to 8 mg of dexchlorpheniramine maleate, from NLT 20 finely powdered Tablets, to a 250-mL separator. Mix with 50 mL of water for 10 min, adjust with sodium hydroxide solution (1 in 10) to a pH of 11, and cool to room temperature. Extract the mixture with two 75-mL portions of solvent hexane, and combine the extracts in a second separator. Extract the solvent hexane solution with three 50-mL portions of *Diluent*, combining the *Diluent* extracts in a 200-mL volumetric flask. Add *Diluent* to volume.

Instrumental conditions

Analytical wavelength: Maximum absorbance at about 264 nm

Cell: 1 cm

Blank: *Diluent*

Analysis

Samples: *Standard solution* and *Sample solution*

Concomitantly determine the absorbance of the *Standard solution* and *Sample solution*.

Calculate the percentage of the labeled amount of dexchlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) in the portion of Tablets taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Dexchlorpheniramine Maleate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of dexchlorpheniramine maleate in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: Water; 500 mL

Apparatus 2: 50 rpm

Time: 45 min

Solution A: Sodium hydroxide solution (1 in 2)

Internal standard solution: 90 µg/mL of dexbrompheniramine maleate in water

Standard stock solution: 12.5 µg/mL of USP Dexchlorpheniramine Maleate RS in water

Standard solution: Pipet 5 mL of the *Standard stock solution* into a 50-mL centrifuge tube, and add 10.0 mL water and 1.0 mL *Internal standard solution.* Adjust with *Solution A* to a pH of 11 ± 0.1, and add 3.0 mL of chromatographic hexane. Insert the stopper in the tube, shake by mechanical means for 3 min, centrifuge, and use the clear supernatant hexane layer.

Sample solution: Pipet 15 mL of a portion of the solution under test into a 50-mL centrifuge tube, and add 1.0 mL of *Internal standard solution.* Adjust with *Solution A* to a pH of 11 ± 0.1, and add 3.0 mL of chromatographic hexane. Insert the stopper in the tube, shake by mechanical means for 3 min, centrifuge, and use the clear supernatant hexane layer.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 2-mm × 1.8-m; contains a packing consisting of 1.2% phase G16 and 0.5% potassium hydroxide on support S1AB

Temperatures

Column: 205°

Injector: 250°

Detector: 250°

Flow rate: 60 mL/min

Carrier gas: Helium

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for dexchlorpheniramine and dexbrompheniramine are about 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.9 between dexchlorpheniramine and dexbrompheniramine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the quantity of dexchlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) dissolved by comparing the peak response ratios.

Tolerances: NLT 75% (*Q*) of the labeled amount of dexchlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. Store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Dexchlorpheniramine Maleate RS

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

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

Chromatographic Database Information: Chromatographic Database

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