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Pseudoephedrine Hydrochloride, Carbinoxamine Maleate, and Dextromethorphan Hydrobromide Oral Solution

DEFINITION

Pseudoephedrine Hydrochloride, Carbinoxamine Maleate, and Dextromethorphan Hydrobromide Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amounts of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$), dextromethorphan hydrobromide ($C_{18}H_{25}NO \cdot HBr$), and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

IDENTIFICATION

• **A.** The retention times of the carbinoxamine maleate and dextromethorphan hydrobromide peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay* for *Carbinoxamine Maleate and Dextromethorphan Hydrobromide*.

• **B.** The retention time of the pseudoephedrine hydrochloride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay* for *Pseudoephedrine Hydrochloride*.

ASSAY

• **Carbinoxamine Maleate and Dextromethorphan Hydrobromide**

Buffer: Dissolve about 4.4 g of dibasic potassium phosphate in 1000 mL of water. Adjust with phosphoric acid to a pH of 5.5.

Mobile phase: Methanol and *Buffer* (600:400)

Standard solution: 0.1 mg/mL of carbinoxamine maleate and 0.3 mg/mL of dextromethorphan hydrobromide from USP Carbinoxamine Maleate RS and USP Dextromethorphan Hydrobromide RS in water

Sample solution: Nominally 0.1 mg/mL of carbinoxamine maleate and 0.3 mg/mL of dextromethorphan hydrobromide from a suitable volume of Oral Solution in water

Chromatographic system

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

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 25-cm; packing L9

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for dextromethorphan and carbinoxamine are 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between carbinoxamine and dextromethorphan

Tailing factor: NMT 2.0 for the dextromethorphan peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of the labeled amounts of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$) and of dextromethorphan hydrobromide ($C_{18}H_{25}NO \cdot HBr$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of the appropriate analyte from the *Sample solution*

r_S = peak response of the appropriate analyte from the *Standard solution*

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C_S = concentration of the appropriate Reference Standard in the *Standard solution* (mg/mL)

C_U = nominal concentration of the appropriate analyte in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$) and 90.0%–110.0% of the labeled amount of dextromethorphan hydrobromide ($C_{18}H_{25}NO \cdot HBr$)

• **Pseudoephedrine Hydrochloride**

Buffer: Dissolve about 4.4 g of dibasic potassium phosphate in 1000 mL of water. Adjust with phosphoric acid to a pH of 5.5.

Mobile phase: Methanol and *Buffer* (600:400)

Standard solution: 1.2 mg/mL of pseudoephedrine hydrochloride from USP Pseudoephedrine Hydrochloride RS in water

Sample solution: Nominally 1.2 mg/mL of pseudoephedrine hydrochloride from a suitable volume of Oral Solution in water

Chromatographic system

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

Mode: LC

Detector: UV 257 nm

Column: 4.6-mm × 25-cm; packing L9

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of pseudoephedrine from the *Sample solution*

r_S = peak response of pseudoephedrine from the *Standard solution*

C_S = concentration of USP Pseudoephedrine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of pseudoephedrine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$)

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩**

For single-unit containers

Acceptance criteria: Meets the requirements

• **Deliverable Volume ⟨698⟩**

For multiple-unit containers

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^2 cfu/g, the total combined molds and yeasts count does not exceed 10^1 cfu/g, and it meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.

• **pH ⟨791⟩:** 3.0–5.0

• **Alcohol Determination,** *Method II* **⟨611⟩** (if present)**:** 90.0%–110.0% of the labeled amount of alcohol (C_2H_5OH) is found.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.

• **USP Reference Standards ⟨11⟩**

USP Carbinoxamine Maleate RS

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