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Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Oral Solution

» Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) and pseudoephedrine hydrochloride ($C_{10}H_{15}NO \cdot HCl$).

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

USP Reference standards ⟨11⟩—
USP Chlorpheniramine Maleate RS
USP Pseudoephedrine Hydrochloride RS

Identification—

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

B: The retention time of the major peak for pseudoephedrine hydrochloride in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* in the *Assay for pseudoephedrine hydrochloride.*

Uniformity of dosage units ⟨905⟩—
FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩—
FOR ORAL SOLUTION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

Assay for chlorpheniramine maleate—

Mobile phase, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay for chlorpheniramine maleate* under *Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Extended-Release Capsules*.

Standard preparation—Dissolve an accurately weighed quantity of USP Chlorpheniramine Maleate RS in water to obtain a solution having a known concentration of about 1 mg per mL. Transfer 1.0 mL of this solution to a 100-mL volumetric flask, add 80 mL of *Mobile phase,* dilute with water to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 1 mg of chlorpheniramine maleate, to a 100-mL volumetric flask. Add about 80 mL of *Mobile phase,* dilute with water to volume, mix, and filter.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the chlorpheniramine peaks. Calculate the quantity, in mg, of chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$) in the portion of Oral Solution taken by the formula:

$$(100C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Chlorpheniramine Maleate RS in that *Standard preparation; V* is the volume, in mL, of Oral Solution taken for the *Assay preparation;* and r_U and r_S are the chlorpheniramine peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Assay for pseudoephedrine hydrochloride—

Mobile phase, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay for chlorpheniramine maleate* under *Chlorpheniramine Maleate and Pseudoephedrine Hydrochloride Extended-Release Capsules*.

Standard preparation—Dissolve an accurately weighed quantity of USP Pseudoephedrine Hydrochloride RS in water to obtain a solution having a known concentration of about 1.5 mg per mL. Transfer about 1.0 mL of this solution to a 10-mL volumetric flask, add 8 mL of *Mobile phase,* dilute with water to volume, and mix.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 15 mg of pseudoephedrine hydrochloride, to a 100-mL volumetric flask. Add 80 mL of *Mobile phase,* dilute with water to volume, mix, and filter.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the pseudoephedrine peaks. Calculate the quantity, in mg, of pseudoephedrine

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hydrochloride ($C_{10}H_{15}NO \cdot HCl$) in the portion of Oral Solution taken by the formula:

$$100(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Pseudoephedrine Hydrochloride RS in the *Standard preparation; V* is the volume, in mL, of Oral Solution taken for the *Assay preparation;* and r_U and r_S are the pseudoephedrine peak responses obtained from 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
CHLORPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE HYDROCHLORIDE ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 30(1)

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