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Guaifenesin Oral Solution

DEFINITION
Guaifenesin Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of guaifenesin ($C_{10}H_{14}O_4$).

IDENTIFICATION

Change to read:

• **▲A.▲** (USP 1-MAY-2022) The retention time of the guaifenesin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Add the following:

▲• B. The UV spectrum of the guaifenesin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-May-2022)

ASSAY

Change to read:

• **PROCEDURE**

Mobile phase: Methanol, glacial acetic acid, and water (40: 1.5: 60)

Benzoic acid solution: 2 mg/mL of benzoic acid in methanol

Standard stock solution: 2 mg/mL of USP Guaifenesin RS in water. Shake to dissolve.

Standard solution: 40 µg/mL of USP Guaifenesin RS prepared as follows. Transfer 2.0 mL of the *Standard stock solution* to a 100-mL volumetric flask. Add 45 mL of methanol and dilute with water to volume.

System suitability solution: 100 µg/mL of benzoic acid and 40 µg/mL of USP Guaifenesin RS prepared as follows. Transfer 5.0 mL of *Benzoic acid solution* and 2.0 mL of *Standard stock solution* to a 100-mL volumetric flask. Add 40 mL of methanol and dilute with water to volume.

Sample stock solution: Nominally 2 mg/mL of guaifenesin from Oral Solution in water prepared as follows. Transfer a suitable volume of Oral Solution, equivalent to 200 mg of guaifenesin, to a 100-mL volumetric flask. Dilute with water to volume

Sample solution: Nominally 40 µg/mL of guaifenesin prepared as follows. Transfer 2.0 mL of the *Sample stock solution* to a 100-mL volumetric flask. Add 45 mL of methanol and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2022)

Column: 4.6-mm × 25-cm; 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *System suitability solution*

[NOTE—The relative retention times for guaifenesin and benzoic acid are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between guaifenesin and benzoic acid, *System suitability solution*

Relative standard deviation: NMT ▲1.0%,▲ (USP 1-May-2022) *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of labeled amount of guaifenesin ($C_{10}H_{14}O_4$) 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 guaifenesin from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

• **Alcohol Determination ⟨611⟩, *Method I*:** (if present) 90.0–115.0% of the labeled amount of alcohol (C_2H_5OH)

PERFORMANCE TESTS

• **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

SPECIFIC TESTS

Change to read:

• **pH ⟨791⟩:** 2.3–▲6.5▲ (USP 1-May-2022)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers. ▲Do not refrigerate.▲ (USP 1-May-2022)

• **USP Reference Standards ⟨11⟩**

USP Guaifenesin RS

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

Topic/Question	Contact	Expert Committee
GUAIFENESIN ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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