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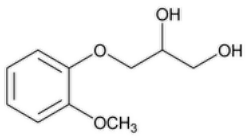
Guaifenesin



$C_{10}H_{14}O_4$ 198.22

1,2-Propanediol, 3-(2-methoxyphenoxy)-(±)-;

(±)-3-(*o*-Methoxyphenoxy)-1,2-propanediol CAS RN®: 93-14-1; UNII: 495W7451VQ.

DEFINITION

Guaifenesin contains NLT 98.0% and NMT 102.0% of guaifenesin ($C_{10}H_{14}O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197A or 197K▲ (CN 1-May-2020)

Change to read:

• **B.** ▲Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U▲ (CN 1-May-2020)

Sample solution: 40 µg/mL in methanol

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Solution A: Glacial acetic acid and water (1:99)

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
32	50	50
35	80	20

System suitability solution: 0.5 mg/mL of USP Guaifenesin RS and 0.02 mg/mL of USP Guaiacol RS in *Solution B*

Standard solution: 0.5 mg/mL of USP Guaifenesin RS in *Solution B*

Sample solution: 0.5 mg/mL of Guaifenesin in *Solution B*

Chromatographic system

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

Mode: LC

Detector: UV 276 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

[Note—See *Table 2* for relative retention times.]

Suitability requirements

Resolution: NLT 3 between guaifenesin and guaiacol, *System suitability solution*

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Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of guaifenesin ($C_{10}H_{14}O_4$) in the portion of Guaifenesin 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* (mg/mL)

C_U = concentration of Guaifenesin in the *Sample solution* (mg/mL)

To this value, add the percentage of guaifenesin β-isomer found in the test for *Organic Impurities*.

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

Change to read:

• **Organic Impurities**

Solution A, Solution B, Mobile phase, System suitability solution, Standard solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample solution: 2 mg/mL of Guaifenesin in *Solution B*

Diluted sample solution: 0.02 mg/mL of Guaifenesin from the *Sample solution* in *Solution B*

Analysis

Samples: *Sample solution* and *Diluted sample solution*

[Note—See *Table 2* for relative retention times.]

[Note—All of the peaks are baseline resolved.]

Calculate the percentage of each individual impurity in the portion of Guaifenesin taken:

$$\text{Result} = (r_U/r_S) \blacktriangle\times (C_S/C_U)\blacktriangle_{\text{(ERR 1-Nov-2018)}} \times (1/F) \times 100$$

r_U = peak response of each individual impurity from the *Sample solution*

r_S = peak response of guaifenesin from the *Diluted sample solution*

$\blacktriangle C_S$ = concentration of guaifenesin in the *Diluted sample solution*

C_U = concentration of guaifenesin in the *Sample solution*▲ (ERR 1-Nov-2018)

F = relative response factor

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Guaifenesin β-isomer[a]	0.9	1.0	1.5
Guaifenesin	1.0	—	—
Guaiacol	1.4	1.6	0.03
Any individual unspecified impurity	—	1.0	0.5
Total impurities[b]	—	—	1.0

[a] 2-(2-Methoxyphenoxy)-1,3-propanediol.

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[b] Excluding guaifenesin β-isomer and guaiacol.

SPECIFIC TESTS

- **Loss on Drying** ⟨731⟩

  Analysis: Dry under vacuum (NLT 10 mm of mercury) at 60° to a constant weight.

  Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩

  USP Guaiacol RS

  USP Guaifenesin RS

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

Topic/Question	Contact	Expert Committee
GUAIFENESIN	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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