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Guaifenesin Compounded Injection, Veterinary

DEFINITION

Guaifenesin Compounded Injection, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of guaifenesin ($C_{10}H_{14}O_4$).

Prepare Guaifenesin Compounded Injection, Veterinary 50 mg/mL as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*.)

Guaifenesin	50 g
Propylene Glycol	20 mL
Dextrose Injection (5%), a sufficient quantity to make	1000 mL

Accurately weigh the *Guaifenesin* and transfer it into a sterile depyrogenated beaker. Add the *Propylene Glycol* to the *Guaifenesin* and mix well to wet. Add about 200 mL of the *Dextrose Injection (5%)* to the guaifenesin mixture and heat the mixture briefly, not to exceed 50°, for solubilization. Bring to final volume with the *Dextrose Injection (5%)*. Pass through an inline sterile membrane filter of 0.22-µm pore size into a sterile polyvinyl chloride intravenous bag. [Note—Use a sterilizing filter that is compatible with glycol-containing solutions.]

ASSAY

• **Procedure**

Solution A: Dissolve 2.5 mL of glacial acetic acid in 1000 mL of water.

Mobile phase: Methanol and *Solution A* (35:65)

Diluent: Methanol and water (35:65)

Standard solution: 1 mg/mL of guaifenesin prepared from USP Guaifenesin RS in *Diluent*

Sample solution: Transfer 1 mL of Injection, Veterinary into a 50-mL volumetric flask, dilute with *Diluent* to volume, and mix well to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 276 nm

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

Column temperature: 25°

Flow rate: 1.0 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for guaifenesin is about 16.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of guaifenesin ($C_{10}H_{14}O_4$) in the portion of Injection, Veterinary 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 = nominal concentration of guaifenesin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.6–4.6

• **Sterility Tests** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** It meets the requirements.

• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 0.05 USP Endotoxin Units/mg of guaifenesin

• **Particulate Matter in Injections** ⟨788⟩**:** It meets the requirements.

Change to read:

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in a sterile polyvinyl chloride intravenous bag. Store at controlled room temperature or at 37°. [Note—Do not store at cold temperatures as precipitation may occur.]

• **Beyond-Use Date:** ▲In the absence of passing a sterility and endotoxins test, the beyond-use dates (BUDs) in *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩ apply. After successful completion of sterility and endotoxins testing, NMT 90 days after the date on which it was compounded when stored at controlled room temperature or NMT 7 days after the date on which it was compounded when stored at 37°.▲

(CN 1-May-2020)

• **Labeling:** Label it to indicate that it is for veterinary use only. The label states that it is intended for injection only by the intravenous route. Label it to state the *Beyond-Use Date*.

• **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 COMPOUNDED INJECTION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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