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Guaifenesin for Injection

» Guaifenesin for Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of guaifenesin ($C_{10}H_{14}O_4$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, and store at controlled room temperature.

Labeling—It meets the requirements for Labeling 〈7〉, Labels and Labeling for Injectable Products**. 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 in horses.**

USP REFERENCE STANDARDS 11—

USP Guaifenesin RS

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Change to read:

Identification, ▲Spectroscopic Identification Tests 〈197〉, Infrared Spectroscopy: 197K▲ **(CN 1-May-2020).**

Constituted solution—At the time of use, it meets the requirements for Injections and Implanted Drug Products 1, Specific Tests, Completeness and clarity of solutions**.**

STERILITY TESTS 71—It meets the requirements when tested as directed for Membrane Filtration **under** Test for Sterility of the Product to be Examined**.**

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BACTERIAL ENDOTOXINS TEST 85—It contains not more than 0.05 Endotoxin Unit per mg of guaifenesin.

Assay—

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Standard preparation—**Dissolve an accurately weighed quantity of USP Guaifenesin RS in chloroform to obtain a solution having a known concentration of about 40 µg per mL.**

Assay preparation—**Constitute a container of Guaifenesin for Injection with a volume of warm (30° to 35°) water, accurately measured, corresponding to the volume of solvent specified in the labeling. Transfer an accurately measured volume of the constituted solution, equivalent to about 100 mg of guaifenesin, to a 250-mL separator containing 10 mL of a saturated solution of sodium bicarbonate. Extract with four 25-mL portions of chloroform, combining the chloroform extracts in a second 250-mL separator. Wash the combined chloroform extracts with 5 mL of 1 N hydrochloric acid. Filter the washed chloroform extracts through chloroform-moistened filter paper, collecting the filtrate in a 100-mL volumetric flask. Dilute with chloroform to volume, and mix. Transfer 4.0 mL of this solution to a second 100-mL volumetric flask, dilute with chloroform to volume, and mix.**

Procedure—**Concomitantly determine the absorbances of the** Standard preparation **and the** Assay preparation **at the wavelength of maximum absorbance at about 276 nm, using chloroform to zero the instrument. Calculate the quantity, in mg, of guaifenesin ($C_{10}H_{14}O_4$) in each mL of the constituted solution of Guaifenesin for Injection taken by the formula:**

$$2.5(C/V)(A_U/A_S)$$

in which C **is the concentration, in µg per mL, of USP Guaifenesin RS in the** Standard preparation, V **is the volume, in mL, of constituted solution taken to prepare the** Assay preparation**, and** A_U **and** A_S **are the absorbances of 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
GUAIFENESIN FOR INJECTION	Documentary Standards Support	SM32020Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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