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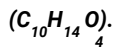
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Guaifenesin for Injection

» Guaifenesin for Injection contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of guaifenesin

**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](#).**BACTERIAL ENDOTOXINS TEST 85**—It contains not more than 0.05 Endotoxin Unit per mg of guaifenesin.**Assay**—**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 absorbance 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/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	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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USP-NF Guaifenesin for Injection

<https://trungtamthuoc.com>

Most Recently Appeared in:

Pharmacopeial Forum: Volume No. Information currently unavailable

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