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Guaifenesin Tablets

» Guaifenesin Tablets contain 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 tight containers.

USP Reference standards ⟨11⟩—

USP Guaifenesin RS

Identification—

A: Triturate a quantity of finely powdered Tablets, equivalent to about 100 mg of guaifenesin, with 10 mL of chloroform, filter, and evaporate 1 mL of the filtrate on a watch glass. Mix the residue with 1 drop of formaldehyde and a few drops of sulfuric acid: a deep cherry-red to purple color is produced.

B: The retention time of the guaifenesin peak in the chromatogram of the *Assay preparation* corresponds to that of the guaifenesin peak in the chromatogram of the *Standard preparation* as obtained in the *Assay*.

Dissolution, *Procedure for a Pooled Sample* ⟨711⟩—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{10}H_{14}O_4$ dissolved in filtered portions of the solution under test from UV absorbances at the wavelength of maximum absorbance at about 274 nm in comparison with a Standard solution having a known concentration of USP Guaifenesin RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{10}H_{14}O_4$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Mobile phase—Prepare a suitable filtered and degassed mixture of water, methanol, and glacial acetic acid (60:40:1.5). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Benzoic acid solution—Dissolve a suitable quantity of benzoic acid in methanol to obtain a solution containing about 2 mg per mL.

Resolution solution—Dissolve a suitable quantity of guaifenesin in water, with shaking, to obtain a solution containing about 2 mg per mL. Transfer 2.0 mL of this solution and 5.0 mL of *Benzoic acid solution* to a 100-mL volumetric flask, add 40 mL of methanol, dilute with water to volume, and mix to obtain a solution containing about 40 µg of guaifenesin and 100 µg of benzoic acid per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Guaifenesin RS quantitatively in water, with shaking, to obtain a solution having a known concentration of about 2 mg per mL. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, add 45 mL of methanol, dilute with water to volume, and mix to obtain a *Standard preparation* having a known concentration of about 40 µg per mL.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 200 mg of guaifenesin, to a 100-mL volumetric flask, add about 60 mL of water, and shake for about 15 minutes. Dilute with water to volume, filter if necessary to obtain a clear solution, and mix. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, add 45 mL of methanol, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 276-nm detector and a 4.6-mm × 25-cm column that contains 10-µm packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution,* and record the peak responses as directed under *Procedure:* the resolution, *R,* between the guaifenesin and benzoic acid peaks is not less than 3.0 (the relative retention times are about 0.7 for guaifenesin and 1.0 for benzoic acid). Chromatograph the *Standard preparation*, and record the peak responses as directed under *Procedure:* the relative standard deviation for replicate injections is not more than 2.5%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of guaifenesin ($C_{10}H_{14}O_4$) in the portion of Tablets taken by the formula:

$$5C(r_U/r_S)$$

in which *C* is the concentration, in µg per mL, of USP Guaifenesin RS in the *Standard preparation,* and r_U and r_S are the peak responses obtained from 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 TABLETS	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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