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Guaifenesin Capsules

» Guaifenesin Capsules 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 portion of the contents of Capsules, 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 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_{10}H_{14}O_4$ dissolved, employing the procedure set forth in the *Assay*, making any necessary modifications.

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, Benzoic acid solution, Resolution solution, Standard preparation, and Chromatographic system—Proceed as directed in the [Assay](#) under [Guaifenesin Tablets](#).

Assay preparation—Transfer, as completely as possible, the contents of not less than 20 Capsules to a suitable tared container, and determine the average content weight per Capsule. Mix the combined contents, and transfer an accurately weighed portion, equivalent to about 200 mg of guaifenesin, to a 100-mL volumetric flask. Proceed as directed for *Assay preparation* in the [Assay](#) under [Guaifenesin Tablets](#), beginning with “add about 60 mL of water.”

Procedure—Proceed as directed for *Procedure* in the [Assay](#) under [Guaifenesin Tablets](#). Calculate the quantity, in mg, of guaifenesin ($C_{10}H_{14}O_4$) in the portion of Capsule contents taken by the formula:

$$5C(r_u/r_s)$$

in which the terms are as defined therein.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
GUAIFENESIN CAPSULES	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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