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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	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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