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Dyphylline and Guaifenesin Tablets

» Dyphylline and Guaifenesin Tablets contain not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of dyphylline ($C_{10}H_{14}N_4O_4$) and guaifenesin ($C_{10}H_{14}O_4$).

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11).—

[USP Dyphylline RS](#)
[USP Guaifenesin RS](#)

Identification.—

- A:** Triturate a quantity of finely powdered Tablets, equivalent to about 100 mg of dyphylline, with 20 mL of water, and transfer to a test tube. Add 2.0 mL of 2 N sodium hydroxide and 2 drops of potassium permanganate TS: a green color is produced.
- B:** Triturate a quantity of finely powdered Tablets, equivalent to about 100 mg of guaifenesin, with 10 mL of chloroform, filter, and on a watch glass evaporate 1 mL of the filtrate, on a steam bath, to dryness. To the residue add 1 drop of formaldehyde TS and a few drops of sulfuric acid: a deep cherry-red to purple color is produced.
- C:** The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those 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 amounts of dyphylline ($C_{10}H_{14}N_4O_4$) and guaifenesin ($C_{10}H_{14}O_4$) dissolved, using the procedure set forth in the Assay, making any necessary modifications.
Tolerances—Not less than 75% (*Q*) of the labeled amounts of $C_{10}H_{14}N_4O_4$ and $C_{10}H_{14}O_4$ are dissolved in 45 minutes.

UNIFORMITY OF DOSAGE UNITS (905): meet the requirements.

Assay.—

Mobile phase, Resolution solution, and Standard preparation—Prepare as directed in the Assay under [Dyphylline and Guaifenesin Oral Solution](#).
Assay preparation—Weigh and finely powder not fewer than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of guaifenesin, to a 100-mL volumetric flask, add about 80 mL of *Mobile phase*, sonicate for 30 minutes, and shake by mechanical means for an additional 30 minutes. Dilute with *Mobile phase* to volume, mix, and pass through a membrane filter having a 0.45- μ m or finer porosity, discarding the first 10 mL of the filtrate. Transfer 5.0 mL of the clear filtrate to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.
Chromatographic system—Prepare as directed in the Assay under [Dyphylline and Guaifenesin Oral Solution](#), except omit the use of the guard column.
Procedure—Proceed as directed in the Assay under [Dyphylline and Guaifenesin Oral Solution](#). Calculate the quantities, in mg, of dyphylline ($C_{10}H_{14}N_4O_4$) and guaifenesin ($C_{10}H_{14}O_4$) in the portion of Tablets taken by the formula:

$$1000C(r_U/r_S)$$

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
DYPHYLLINE AND GUAIFENESIN TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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