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Theophylline and Guaifenesin Oral Solution

» Theophylline and Guaifenesin Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of anhydrous theophylline ($C_7H_8N_4O_2$) and not less than 86.7 percent and not more than 113.3 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
USP Theophylline RS

Identification—Transfer a volume of Oral Solution, equivalent to about 150 mg of theophylline, to a separator, add 15 mL of water, and proceed as directed in the *Identification* test under *Theophylline and Guaifenesin Capsules*, beginning with "To a second separator."

Alcohol Determination, *Method II* ⟨611⟩*(if present)*: between 90.0% and 110.0% of the labeled amount of C_2H_5OH, determined by the gas-liquid chromatographic procedure, acetone being used as the internal standard.

Assay—

pH 6.5 buffer solution and *Mobile phase*—Prepare as directed in the *Assay* under *Theophylline and Guaifenesin Capsules*.

Caffeine solution—Dissolve about 400 mg of caffeine in 1000 mL of a mixture of methanol and water (90:10), and mix.

Standard preparation—Dissolve an accurately weighed quantity of USP Theophylline RS in *pH 6.5 buffer solution*, and dilute quantitatively with *pH 6.5 buffer solution* to obtain a solution (*Solution T*) having a known concentration of about 900*J* µg per mL, in which *J* is the ratio of the labeled amount of theophylline to that of guaifenesin. Transfer about 90 mg of USP Guaifenesin RS, accurately weighed, to a 200-mL volumetric flask, add about 150 mL of *pH 6.5 buffer solution*, shake to dissolve, dilute with *pH 6.5 buffer solution* to volume, and mix. Pipet 10 mL of this solution and 5 mL of *Solution T* into a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a *Standard preparation* having known concentrations of about 90 µg of guaifenesin and about 90*J* µg of theophylline per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 90 mg of guaifenesin, to a 200-mL volumetric flask, dilute with *pH 6.5 buffer solution* to volume, and mix. Transfer 10.0 mL of this solution to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 280-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. Chromatograph a mixture of 4 mL of *Standard preparation* and 1 mL of *Caffeine solution*, and record the peak responses as directed for *Procedure:* the resolution, *R,* between the theophylline and caffeine peaks is not less than 3.0, and the relative standard deviation for replicate injections is not more than 2.0 for theophylline and not more than 2.5% for guaifenesin.

Procedure—Proceed as directed in the *Assay* under *Theophylline and Guaifenesin Capsules*. Calculate the quantities, in mg, of anhydrous theophylline ($C_7H_8N_4O_2$) and guaifenesin ($C_{10}H_{14}O_4$) per mL of the Oral Solution taken by the formula:

$$(C/V)(r_U/r_S)$$

in which C is the concentration, in µg per mL, of the appropriate USP Reference Standard in the *Standard preparation*, V is the volume, in mL, of Oral Solution taken, and r_U and r_S are the peak responses of the corresponding analyte in 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
THEOPHYLLINE AND GUAIFENESIN ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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