Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2015
Document Type: USP Monographs
DocId: GUID-E15D06AC-5057-4F20-BBBC-50FCCE1BBEEF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M28820_01_01
DOI Ref: xgq82

Dyphylline and Guaifenesin Oral Solution

DEFINITION

Dyphylline and Guaifenesin Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amounts of dyphylline ($C_{10}H_{14}N_4O_4$) and guaifenesin ($C_{10}H_{14}O_4$).

IDENTIFICATION

- **A.** The UV spectra of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.
- **B.** The retention times of the major peaks of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Buffer: 0.01 M monobasic potassium phosphate

Mobile phase: Methanol and *Buffer* (21:79)

System suitability solution: 0.1 mg/mL each of USP Guaifenesin RS and USP Dyphylline RS and 0.01 mg/mL of guaiacol in *Mobile phase*

Standard solution: 0.1 mg/mL of USP Guaifenesin RS and 0.1*J* mg/mL of USP Dyphylline RS in *Mobile phase*, *J* being the ratio of the labeled amount of dyphylline to that of guaifenesin

Sample solution: Nominally 0.1 mg/mL of guaifenesin, prepared as follows. Transfer 100 mg of guaifenesin from a volume of Oral Solution to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume. Transfer 5.0 mL of this solution to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 230 nm. For *Identification* test *A*, use a diode array detector in the range of 200–400 nm.

Columns

Guard: Packing L1

Analytical: 4.6-mm × 15-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for dyphylline, guaiacol, and guaifenesin are about 0.25, 0.7, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.8 between the guaiacol and guaifenesin peaks; NLT 9.0 between the guaiacol and dyphylline peaks, *System suitability solution*

Relative standard deviation: NMT 2.0% for both dyphylline and guaifenesin, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of the labeled amounts of dyphylline ($C_{10}H_{14}N_4O_4$) and guaifenesin ($C_{10}H_{14}O_4$) in the portion of Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of dyphylline or guaifenesin from the *Sample solution*

r_S = peak response of dyphylline or guaifenesin from the *Standard solution*

C_S = concentration of USP Dyphylline RS or USP Guaifenesin RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of dyphylline or guaifenesin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0% of the labeled amount of dyphylline ($C_{10}H_{14}N_4O_4$) and 90.0%–110.0% of the labeled amount of guaifenesin ($C_{10}H_{14}O_4$)

OTHER COMPONENTS

• **Alcohol Determination** *Method IIb*⟨611⟩**:** 90.0%–110.0% of the labeled amount of alcohol (C_2H_5OH)

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.0–7.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Alcohol Determination—Acetonitrile RS
USP Alcohol Determination‡Alcohol RS
USP Dyphylline RS
USP Guaifenesin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DYPHYLLINE AND GUAIFENESIN ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(1)

Current DocID: GUID-E15D06AC-5057-4F20-BBBC-50FCCE1BBEEF_1_en-US
DOI: https://doi.org/10.31003/USPNF_M28820_01_01
DOI ref: xgq82