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Acetylcysteine Solution

DEFINITION

Acetylcysteine Solution is a sterile solution of Acetylcysteine in water, prepared with the aid of Sodium Hydroxide. It contains NLT 90.0% and NMT 110.0% of the labeled amount of acetylcysteine ($C_5H_9NO_3S$).

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Sample solution: Place 10 mL in a suitable beaker, and adjust to a pH of 2 (pH indicator paper), using 3 N hydrochloric acid. Add up to 2 g of finely powdered sodium chloride, in two portions of 200 mg each initially and then in smaller portions of 25 mg, stirring after each addition until the sodium chloride dissolves and a precipitate is formed. The precipitate appears as a very fine powder, and the solution turns cloudy. If no precipitate forms, add an additional drop of 3 N hydrochloric acid, and stir until the precipitate forms. Allow to stand at room temperature for 15 min, and collect the residue by suction filtration. Use the acetylcysteine so obtained after being dried at a pressure of 50 mm of mercury at 70° for 4 h.

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Solution A: 0.5 mg/mL of sodium metabisulfite solution in water, freshly prepared

Solution B: 0.5 mg/mL of sodium bisulfite solution

Mobile phase: 6.8 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0.

Internal standard solution: 5 mg/mL of [USP L-Phenylalanine RS](#) in *Solution A*

Standard stock solution: 10 mg/mL of [USP Acetylcysteine RS](#) in *Solution A*

Standard solution: 0.5 mg/mL of [USP Acetylcysteine RS](#) and 0.25 mg/mL of [USP L-Phenylalanine RS](#) in *Solution A* from *Standard stock solution* and *Internal standard solution*

Sample stock solution: Equivalent to 10 mg/mL of acetylcysteine from the volume of *Solution* in *Solution B*

Sample solution: 0.5 mg/mL of acetylcysteine and 0.25 mg/mL of [USP L-Phenylalanine RS](#) in *Solution A* from *Sample stock solution* and *Internal standard solution*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 214 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 5 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 6 between acetylcysteine and L-phenylalanine

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—The relative retention times for acetylcysteine and L-phenylalanine are about 0.5 and 1.0, respectively.]

Calculate the percentage of the labeled amount of acetylcysteine ($C_5H_9NO_3S$) in the portion of *Solution* taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of acetylcysteine to L-phenylalanine from the *Sample solution*

R_S = peak response ratio of acetylcysteine to L-phenylalanine from the *Standard solution*

C_S = concentration of [USP Acetylcysteine RS](#) in the *Standard solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 6.0–7.5
- [STERILITY TESTS \(71\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in single-unit or multiple-unit tight containers that effectively exclude oxygen, and store at controlled room temperature.
- [USP REFERENCE STANDARDS \(11\)](#).
[USP Acetylcysteine RS](#)
[USP L-Phenylalanine RS](#)

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

Topic/Question	Contact	Expert Committee
ACETYLCYSTEINE SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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