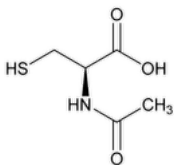


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## Acetylcysteine



$C_5H_9NO_3S$  163.19

L-Cysteine, N-acetyl-;

N-Acetyl-L-cysteine CAS RN®: 616-91-1.

### DEFINITION

Acetylcysteine contains NLT 98.0% and NMT 102.0% of  $C_5H_9NO_3S$ , calculated on the dried basis.

### IDENTIFICATION

*Change to read:*

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

### ASSAY

#### • PROCEDURE

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

**Sodium metabisulfite solution:** 0.5 mg/mL of sodium metabisulfite in water, freshly prepared

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

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

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

**Sample stock solution:** 10 mg/mL of Acetylcysteine in *Sodium metabisulfite solution*

**Sample solution:** 0.5 mg/mL of Acetylcysteine and 0.25 mg/mL of [USP L-Phenylalanine RS](#) in *Sodium metabisulfite solution* 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 size:** 5 µL

#### System suitability

**Sample:** *Standard solution*

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

#### Suitability requirements

**Resolution:** NLT 6 between acetylcysteine and L-phenylalanine

**Relative standard deviation:** NMT 2.0%

#### Analysis

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of acetylcysteine ( $C_5H_9NO_3S$ ) in the portion of Acetylcysteine 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:** 98.0%–102.0% on the dried basis

**IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%

**SPECIFIC TESTS**

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)

**Buffer:** Mix 29.5 mL of 1 N sodium hydroxide, 50 mL of 1 M monobasic potassium phosphate, and sufficient water to make 100 mL. Adjust to a pH of  $7.0 \pm 0.1$  by adding more of either solution, as necessary.

**Sample solution:** In a 25-mL volumetric flask, mix 1.25 g with 1 mL of edetate disodium solution (1 in 100), add 7.5 mL of sodium hydroxide solution (1 in 25), and mix to dissolve. Dilute with *Buffer* to volume.

**Acceptance criteria:**  $+21^{\circ}$  to  $+27^{\circ}$

- [pH \(791\)](#): 2.0–2.8 in a solution (1 in 100)
- [LOSS ON DRYING \(731\)](#): Dry a sample at a pressure of about 50 mm of mercury at  $70^{\circ}$  for 4 h: it loses NMT 1.0% of its weight.

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers, 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	<a href="#">Documentary Standards Support</a>	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM22020 Small Molecules 2

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

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