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*• (ERR 1-Jun-2017) 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)
C_U = nominal concentration of acetylcysteine in the *Sample 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

Acetylcysteine Compounded Solution

DEFINITION
Acetylcysteine Compounded Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of acetylcysteine ($C_5H_9NO_3S$). Prepare Acetylcysteine Compounded Solution 20% as follows (see *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩).

Acetylcysteine	2 g
Edetate Disodium Dihydrate	5.5 mg
Sodium Hydroxide 10% Solution	To adjust pH to 6.5–7.5
Sterile Water for Injection, a sufficient quantity to make	10 mL[a]

[a] It is necessary to adjust the formula and compound an additional amount to completely fill each single-unit container to minimize exposure to oxygen because the preparation is susceptible to oxidation.

Dissolve *Edetate Disodium Dihydrate* in 7 mL of *Sterile Water for Injection*. Slight heating may be necessary. Allow to cool. Dissolve *Acetylcysteine* in the edetate disodium solution. Add *Sodium Hydroxide 10% Solution* dropwise with mixing to adjust the pH to between 6.5 and 7.5. Bring to final volume with *Sterile Water for Injection* and mix well. Pass through a sterile filter of 0.22-µm pore size into single-unit sterile containers. It is necessary to completely fill the container to minimize the amount of oxygen present because the preparation is susceptible to oxidation.

ASSAY
• **PROCEDURE**
Mobile phase: Acetonitrile, phosphoric acid, and water (3: 0.5: 96.5)
Standard solution: 0.4 mg/mL of acetylcysteine prepared from USP Acetylcysteine RS in *Mobile phase*
Sample solution: Transfer 0.4 mL of Solution to a 200-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 200 nm
Column: 4.6-mm × 25-cm; 5-µm packing L96
Column temperature: 15°
Flow rate: 2.0 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*
[NOTE—The retention time for acetylcysteine is about 3.8 min.]
Suitability requirements
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0% for replicate injections
Analysis
Samples: *Standard solution* and *Sample solution*
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 of acetylcysteine from the *Sample solution*
r_S = peak response of acetylcysteine from the *Standard solution*
C_S = concentration of USP Acetylcysteine RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of acetylcysteine in the *Sample solution* (mg/mL)
Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS
• **pH** ⟨791⟩: 6.5–7.5
• **STERILITY TESTS** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration*: Meets the requirements

ADDITIONAL REQUIREMENTS
• **PACKAGING AND STORAGE:** Package in single-unit sterile glass containers and store at controlled room temperature.
• **BEYOND-USE DATE:** In the absence of performing and completing a sterility test, the storage conditions for *High-Risk Level CSPs* in *Pharmaceutical Compounding—Sterile Preparations* ⟨797⟩, *CSP Microbial Contamination*