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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.

Change to read:

• **Beyond-Use Date:** ▲In the absence of performing and completing a sterility test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations* ⟨797⟩*, 14.3 Establishing a BUD for a CSP* apply.▲ (CN 1-Nov-2023) After successful completion of sterility testing, the *Beyond-Use Date* is NMT 60 days after the date on which it was compounded when stored at controlled room temperature.

• **Labeling:** Label it to state the *Beyond-Use Date*. The label indicates that the Solution is not to be used if it contains a precipitate. Label it to state that it is a single-unit container, that it is overfilled with an excess that should be discarded after a measured single dose is used, and to store at controlled room temperature. Label it for inhalation or oral administration only. Label it to state that the preparation may have a disagreeable odor and light purple color that is a result of a chemical reaction that does not affect the strength of the preparation.

• **USP Reference Standards** ⟨11⟩

USP Acetylcysteine RS

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

Topic/Question	Contact	Expert Committee
ACETYLCYSTEINE COMPOUNDED SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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