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Aminocaproic Acid Injection

DEFINITION

Aminocaproic Acid Injection is a sterile solution of Aminocaproic Acid in Water for Injection. It contains NLT 95.0% and NMT 107.5% of the labeled amount of aminocaproic acid ($C_6H_{13}NO_2$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: Mix 2 mL of Injection, added dropwise, with 100 mL of acetone, rapidly stirring the mixture with a glass rod to induce crystallization. Allow the mixture to stand for 15 min, and pass through a sintered-glass filter of medium pore size. Wash the crystals with 25 mL of acetone, apply a vacuum to remove the solvent, dry at 105° for 30 min, and cool. Use the residue.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Transfer 11 g of sodium 1-pentanesulfonate and 40 g of anhydrous sodium sulfate to a 2-L volumetric flask, and dissolve in about 500 mL of water. Add 20 mL of 1 N sulfuric acid and 30 mL of acetonitrile, and dilute with water to volume.

Standard solution: 2.5 mg/mL of USP Aminocaproic Acid RS in *Mobile phase*

System suitability solution: Mix 20 µL of benzyl alcohol with 100 mL of water. Dilute 1.0 mL of this solution with *Standard solution* to 10 mL.

Sample stock solution: Nominally equivalent to 25 mg/mL of aminocaproic acid from a suitable volume of Injection in water

Sample solution: 2.5 mg/mL of *Sample stock solution* in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

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

Suitability requirements

Resolution: NLT 7.0 between benzyl alcohol and aminocaproic acid, *System suitability solution*

[Note—The aminocaproic acid peak elutes before the benzyl alcohol peak.]

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aminocaproic acid ($C_6H_{13}NO_2$) in the portion of Injection taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Aminocaproic Acid RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of aminocaproic acid in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–107.5%

SPECIFIC TESTS

• **pH ⟨791⟩:** 6.0–7.6

• **Bacterial Endotoxins Test ⟨85⟩ :** NMT 0.05 USP Endotoxin Unit/mg of aminocaproic acid

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

• **USP Reference Standards** ⟨11⟩
USP Aminocaproic Acid RS

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

Topic/Question	Contact	Expert Committee
AMINOCAPROIC ACID INJECTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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