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Aminocaproic Acid Oral Solution

DEFINITION

Aminocaproic Acid Oral Solution contains NLT 95.0% and NMT 115.0% of the labeled amount of aminocaproic acid (C₆H₁₃NO₂).

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS** (197), *Infrared Spectroscopy*: 197K

Sample: Mix 1 g of ion-exchange resin (strongly acidic styrene–divinylbenzene cation-exchange resin) with 10 mL of 1 N [hydrochloric acid](#) in a 100-mL beaker. Decant and discard the hydrochloric acid, and wash the resin with five 10-mL portions of [water](#), decanting and discarding the liquid following each washing. Place the washed resin in a 125-mL glass-stoppered, conical flask, and add a volume of Oral Solution, nominally equivalent to 250 mg of aminocaproic acid, and 10 mL of [water](#). Insert the stopper in the flask, and shake by mechanical means for 30 min. Transfer the resin slurry to a sintered-glass funnel of medium pore size. Wash with 100 mL of [water](#), filter by applying suction, and discard the washing. Place a beaker under the stem of the funnel, add 10 mL of 1 N [hydrochloric acid](#) to the resin, stir for 4–5 min, and filter by applying suction. Evaporate the filtrate on a steam bath to dryness, dry at 105° for 1 h, and cool.

Acceptance criteria: The residue meets the requirements.

Add the following:

▲ **B.** The retention time of the aminocaproic acid peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2022)

ASSAY

Change to read:

• **PROCEDURE**

▲ **Solution A:** 10 g/L of [potassium phosphate, monobasic](#) and 0.55 g/L of [sodium 1-heptanesulfonate](#) in [water](#). Adjust with [sodium hydroxide](#) to a pH of 6.8.

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
20	50	50
25	100	0
35	100	0

Standard solution: 0.5 mg/mL of [USP Aminocaproic Acid RS](#) in [water](#)

Sample solution: Nominally 0.5 mg/mL of aminocaproic acid from Oral Solution in [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 40°

Flow rate: 0.7 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of aminocaproic acid ($C_6H_{13}NO_2$) in the portion of Oral Solution taken:

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

r_U = peak response of aminocaproic acid from the *Sample solution*

r_S = peak response of aminocaproic acid 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) ▲ (USP 1-Aug-2022)

Acceptance criteria: 95.0%–115.0%

Add the following:

▲PERFORMANCE TESTS

- [DELIVERABLE VOLUME \(698\)](#): Meets the requirements ▲ (USP 1-Aug-2022)

SPECIFIC TESTS

- [pH \(791\)](#): 6.0–6.5

Add the following:

- ▲ • [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): The total aerobic microbial count is NMT 10^2 cfu/mL. The total yeasts and molds count is NMT 10^1 cfu/mL. It meets the requirements of the test for absence of *Escherichia coli*. ▲ (USP 1-Aug-2022)

ADDITIONAL REQUIREMENTS

Change to read:

- **PACKAGING AND STORAGE:** Preserve in tight containers. ▲Store at controlled room temperature. ▲ (USP 1-Aug-2022)
- [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 ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 51(1)

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