the blank. Treat each as follows. Add 5.0 mL of 1 N hydrochloric acid, and cool in an ice bath. Add 2.0 mL of 0.1 M sodium nitrite dropwise, with stirring, allow to stand for 5 minutes in order for the diazotization reaction to be complete, add quickly to 10.0 mL of a cold solution of guaiacol (freshly prepared by dissolving 0.20 g of guaiacol in 100 mL of 1 N sodium hydroxide), mix, and allow to stand for 30 minutes. Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 450 nm, using the blank to set the instrument: the absorbance of the solution obtained from the *Test preparation* does not exceed that of the solution obtained from the *Standard preparation*, corresponding to not more than 0.002% of volatile diazotizable substances, as *p*-toluidine.

Heavy metals, *Method II* 〈231〉: 0.002%.

Ordinary impurities 〈466〉—

Test solution: alcohol.

Standard solution: alcohol.

Eluant: a mixture of toluene, ethyl acetate, and alcohol (60:20:20), in a nonequilibrated chamber.

Visualization: 1.

Assay—Weigh accurately about 250 mg of Aminobenzoic Acid, and proceed as directed under *Nitrite Titration* 〈451〉. Each mL of 0.1 M sodium nitrite is equivalent to 13.71 mg of $C_7H_7NO_2$.

Aminobenzoic Acid Gel

» Aminobenzoic Acid Gel contains not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of aminobenzoic acid ($C_7H_7NO_2$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards 〈11〉—
USP Aminobenzoic Acid RS

Identification—

A: *Infrared Absorption* 〈197K〉.

B: *Ultraviolet Absorption* 〈197U〉—

Solution: 5 µg per mL.

Medium: alcohol.

Minimum fill 〈755〉: meets the requirements.

pH 〈791〉: between 4.0 and 6.0.

Alcohol content, *Method II* 〈611〉: between 42.3% and 54.0% (w/w) of C_2H_5OH.

Assay—

*Mobile phase—*Mix 300 mL of methanol and 10 mL of glacial acetic acid with 690 mL of water. Allow the mixture to cool, and filter, if necessary, through a suitable microporous membrane filter. Degas the solution.

*Internal standard solution—*Dissolve salicylic acid in methanol, by sonicating, to obtain a solution having a concentration of about 7 mg per mL.

*Standard preparation—*Dissolve, by sonicating, an accurately weighed quantity of USP Aminobenzoic Acid RS in methanol, quantitatively dilute with methanol to obtain a solution having a known concentration of about 0.42 mg per mL, and mix. Pipet 5 mL of this solution and 5 mL of the *Internal standard solution* into a 50-mL volumetric flask, dilute with methanol to volume, and mix. Pass through 0.6-µm filter paper. Throughout the preparation, protect against actinic light.

*Assay preparation—*Transfer an accurately weighed quantity of Gel, equivalent to about 4.2 mg of aminobenzoic acid, to a 100-mL volumetric flask, and add 10.0 mL of *Internal standard preparation* and about 50 mL of methanol. Shake or sonicate, as necessary, dilute with methanol to volume, and mix. Filter, if necessary, through filter paper (Whatman No. 41 or equivalent). Pass through 0.6-µm filter paper. Throughout this preparation, protect against actinic light.

Chromatographic system (see *Chromatography* 〈621〉)—The liquid chromatograph is equipped with a 280-nm detector and a 3.9-mm × 30-cm column that contains packing L11. The flow rate is about 1.0 mL per minute. Chromatograph replicate 15-µL injections of *Standard preparation* until the response ratio variability is within 1.0% of average. The resolution factor is not less than 3.0 between aminobenzoic acid and salicylic acid.

*Procedure—*Separately inject equal volumes (about 15 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The retention time of salicylic acid is about 3.0 relative to that of aminobenzoic acid as 1.0. Calculate the quantity, in mg, of aminobenzoic acid ($C_7H_7NO_2$) in the portion of Gel taken by the formula:

$$100C(R_U / R_S)$$

in which C is the concentration, in mg per mL, of USP Aminobenzoic Acid RS in the *Standard preparation;* and R_U and R_S are the ratios of the peak responses of the aminobenzoic acid peak to the salicylic acid peak obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Aminobenzoic Acid Topical Solution

» Aminobenzoic Acid Topical Solution contains, in each mL, not less than 45 mg and not more than 55 mg of aminobenzoic acid ($C_7H_7NO_2$).

Packaging and storage—Preserve in tight, light-resistant containers.

Identification—

A: To 1 mL of Topical Solution add 1 mL of 1 N sodium hydroxide, and add, in the order named, 0.5 mL of potassium iodide TS, 0.5 mL of 3 N hydrochloric acid, and 0.5 mL of sodium hypochlorite TS: a brown precipitate is formed.

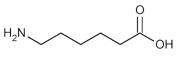
B: To 1 mL of Topical Solution add 2 mL of 3 N hydrochloric acid, and cool to about 10 °. Add 1 mL of sodium nitrite solution (1 in 100), then add a solution prepared by mixing 50 mg of 2-naphthol with 3 mL of sodium hydroxide solution (1 in 10): a red color is produced.

Specific gravity 〈841〉: not less than 0.895 and not more than 0.905.

Alcohol content 〈611〉: between 65% and 75% of C_2H_5OH.

Assay—Transfer 5 mL of Topical Solution, accurately measured, to a suitable open vessel, evaporate on a steam bath to dryness, and proceed as directed under *Nitrite Titration* 〈451〉, beginning with "Add 20 mL of hydrochloric acid." Each mL of 0.1 M sodium nitrite is equivalent to 13.71 mg of $C_7H_7NO_2$.

Aminocaproic Acid



$C_6H_{13}NO_2$ 131.17
Hexanoic acid, 6-amino-.
6-Aminohexanoic acid [60-32-2].

» Aminocaproic Acid contains not less than 98.5 percent and not more than 101.5 per cent of $C_6H_{13}NO_2$, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers. Store at room temperature.

USP Reference standards 〈11〉—
USP Aminocaproic Acid RS

Identification, *Infrared Absorption* 〈197K〉**.**

Water, *Method I* 〈921〉**:** not more than 0.5%.

Residue on ignition 〈281〉**:** not more than 0.1%.

Heavy metals, *Method II* 〈231〉**:** 0.002%.

Assay—

Solution A—Transfer 0.55 g of sodium 1-heptanesulfonate to a 1000-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

Mobile phase—Transfer 10 g of monobasic potassium phosphate to a 1000-mL beaker, dissolve in 300 mL of *Solution A,* add 250 mL of methanol, followed by another 300 mL of *Solution A,* and mix. Adjust the mixture with phosphoric acid to a pH of 2.2. Transfer the whole mixture to a 1000-mL volumetric flask, dilute with *Solution A* to volume, and mix. Filter and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* 〈621〉).

Internal standard solution—Prepare a solution of methionine in water containing 1.25 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of USP Aminocaproic Acid RS in water to obtain a *Stock solution* having a known concentration of 12.5 mg per mL. Transfer 5.0 mL of the *Stock solution* to a 100-mL volumetric flask, add 2.0 mL of the *Internal standard solution,* dilute with water to volume, and mix.

Assay preparation—Transfer an accurately weighed quantity of 1.25 g of Aminocaproic Acid to a 100-mL volumetric flask, dissolve in and dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, add 2.0 mL of *Internal standard solution,* dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* 〈621〉)—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 15-cm column that contains packing L1 and is maintained at 30°. The flow rate is about 0.7 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.76 for aminocaproic acid and 1.0 for methionine; the resolution, *R,* between aminocaproic acid and methionine is not less than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, and allow the *Assay preparation* to elute for not less than two times the retention time of aminocaproic acid. Record the chromatograms, and measure all the peak responses. Calculate the quantity, in g, of $C_6H_{13}NO_2$ in the portion of Aminocaproic Acid taken by the formula:

$$2C(R_U / R_S)$$

in which *C* is the concentration, in mg per mL, of USP Aminocaproic Acid RS in the *Standard preparation;* and R_U and R_S are the ratios of the aminocaproic acid peak response to the internal standard peak response obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Aminocaproic Acid Injection

» Aminocaproic Acid Injection is a sterile solution of Aminocaproic Acid in Water for Injection. It contains not less than 95.0 per cent and not more than 107.5 per cent of the labeled amount of aminocaproic acid ($C_6H_{13}NO_2$).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass.

USP Reference standards 〈11〉—
USP Aminocaproic Acid RS
USP Endotoxin RS

Identification—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 minutes, and pass through a medium-porosity, sintered-glass filter. Wash the crystals with 25 mL of acetone, apply vacuum to remove the solvent, dry at 105° for 30 minutes, and cool: the residue so obtained responds to the *Identification* test under *Aminocaproic Acid.*

Bacterial endotoxins 〈85〉—It contains not more than 0.05 USP Endotoxin Unit per mg of aminocaproic acid.

pH 〈791〉: between 6.0 and 7.6.

Other requirements—It meets the requirements under *Injections* 〈1〉.

Assay—

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, dilute with water to volume, and mix. Filter and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* 〈621〉).

Standard preparation—Dissolve an accurately weighed quantity of USP Aminocaproic Acid RS in *Mobile phase* to obtain a solution having a known concentration of about 2.5 mg per mL.

Resolution solution—Mix 20 µL of benzyl alcohol with 100 mL of water. Dilute 1.0 mL of this solution with the *Standard preparation* to 10 mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 1.25 g of aminocaproic acid, to a 50-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 50-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography* 〈621〉)—The liquid chromatograph is equipped with a 210-nm detector and a 4-mm × 30-cm column that contains packing L1. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution* as directed for *Procedure:* the resolution, *R,* between benzyl alcohol and aminocaproic acid is not less than 7.0. The aminocaproic acid peak elutes prior to the benzyl alcohol peak. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 50 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. Calculate the quantity, in mg, of aminocaproic acid ($C_6H_{13}NO_2$) in each mL of the Injection taken by the formula:

$$500(C / V)(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of USP Aminocaproic Acid RS in the *Standard preparation; V* is the volume, in mL, of Injection taken; and r_U and r_S are the aminocaproic acid peak areas obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Aminocaproic Acid Oral Solution

» Aminocaproic Acid Oral Solution contains not less than 95.0 per cent and not more than 115.0 percent of the labeled amount of aminocaproic acid ($C_6H_{13}NO_2$).