Identification—Proceed as directed for *Aminobenzoate Potassium Capsules*, using 1 g of finely powdered Tablets.

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_7H_6KNO_2$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 270 nm on filtered portions of the solution under test, suitably diluted with *Medium*, in comparison with a Standard solution having a known concentration of USP Aminobenzoate Potassium RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_7H_6KNO_2$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Assay—

Standard preparation—Prepare a solution of USP Aminobenzoate Potassium RS having a known concentration of about 5 µg per mL.

Assay preparation and *Procedure*—Weigh and finely powder not fewer than 20 Tablets. Using a portion of the powdered Tablets, equivalent to about 100 mg of aminobenzoate potassium, proceed as directed in the *Assay* under *Aminobenzoate Potassium Capsules*.

Aminobenzoate Sodium

» Aminobenzoate Sodium contains not less than 98.5 percent and not more than 101.0 per cent of $C_7H_6NNaO_2$, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Aminobenzoate Sodium RS

Identification—

A: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 1 in 100,000.

Medium: 0.001 N sodium hydroxide.

B: Dissolve about 400 mg in 10 mL of water, add 1 mL of 3 N hydrochloric acid, filter, and wash the precipitate with two 5-mL portions of cold water. Recrystallize from alcohol the precipitate so obtained, and dry at 110° for 1 hour: the *p*-aminobenzoic acid so obtained melts between 186° and 189°.

C: A solution (1 in 100) meets the requirements of the flame test for *Sodium* ⟨191⟩.

pH ⟨791⟩: between 8.0 and 9.0, in a solution (1 in 20).

Loss on drying ⟨731⟩—Dry it at 105° for 2 hours: it loses not more than 1.0% of its weight.

Volatile diazotizable substances—

Standard solution—Dissolve 10 mg of *p*-toluidine in 5 mL of methanol in a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 1 mL to a 100-mL volumetric flask, dilute with water to volume, and mix.

Test solution—Transfer 5.0 g of Aminobenzoate Sodium to a suitable flask, and add a volume of 1.25 N sodium hydroxide that is just sufficient to dissolve the test specimen and to render the solution just alkaline to phenolphthalein TS. Dilute with water to 50 mL, and steam-distill the solution, collecting about 95 mL of the distillate in a 100-mL volumetric flask. Dilute with water to volume, and mix.

Procedure—Transfer 20.0-mL portions of the *Standard solution* and the *Test solution* to separate 100-mL beakers, and transfer 20.0 mL of water to a third 100-mL beaker to provide 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 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 at the wavelength of maximum absorbance at about 405 nm, with a suitable spectrophotometer, using the blank to set the instrument: the absorbance of the solution obtained from the *Test solution* does not exceed that of the solution obtained from the *Standard solution*, corresponding to not more than 0.002% of volatile diazotizable substances, as *p*-toluidine.

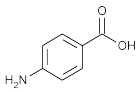
Chloride ⟨221⟩**—**A 1.4-g portion shows no more chloride than corresponds to 0.4 mL of 0.020 N hydrochloric acid (0.02%).

Sulfate ⟨221⟩**—**A 1.4-g portion shows no more sulfate than corresponds to 0.3 mL of 0.020 N sulfuric acid (0.02%).

Heavy metals, *Method II* ⟨231⟩: 0.002%.

Assay—Transfer about 500 mg of Aminobenzoate Sodium, accurately weighed, to a suitable vessel, add 25 mL of water and 25 mL of 3 N hydrochloric acid, mix, and cool in an ice bath. Titrate with 0.1 M sodium nitrite VS, determining the endpoint potentiometrically, using a calomel-platinum electrode system. Each mL of 0.1 M sodium nitrite is equivalent to 15.91 mg of $C_7H_6NNaO_2$.

Aminobenzoic Acid



$C_7H_7NO_2$ 137.14
Benzoic acid, 4-amino.
p-Aminobenzoic acid [150-13-0].

» Aminobenzoic Acid contains not less than 98.5 percent and not more than 101.5 per cent of $C_7H_7NO_2$, calculated on the dried basis.

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: 0.001 N sodium hydroxide.

Melting range ⟨741⟩: between 186° and 189°.

Loss on drying ⟨731⟩**—**Dry it at 105° for 2 hours: it loses not more than 0.2% of its weight.

Residue on ignition ⟨281⟩: not more than 0.1%.

Volatile diazotizable substances—

Standard preparation—Dissolve 10 mg of *p*-toluidine in 5 mL of methanol in a 100-mL volumetric flask, dilute water to volume, and mix. Transfer 1 mL to a 100-mL volumetric flask, dilute with water to volume, and mix.

Test preparation—Transfer 5.0 g of Aminobenzoic Acid to a suitable flask, and add a volume of 1.25 N sodium hydroxide that is just sufficient to dissolve the test specimen and to render the solution just alkaline to phenolphthalein TS. Dilute with water to 50 mL, and steam-distill the solution, collecting about 95 mL of the distillate in a 100-mL volumetric flask. Add water to volume, and mix.

Procedure—Transfer 20.0-mL portions of the *Standard preparation* and the *Test preparation* to separate 100-mL beakers, and transfer 20.0 mL of water to a third 100-mL beaker to provide

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 necessar y, 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 T opical 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 T opical 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.

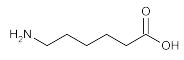
B: To 1 mL of T opical Solution add 2 mL of 3 N hydrochloric acid, and cool to about 10 °. Add 1 mL of sodium nitrite solution (1 in 100), then add a solution prepared by mixing 50 mg of 2-naphthol with 3 mL of sodium hydroxide solution (1 in 10): a red color is produced.

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 T opical Solution, accurately measured, to a suitable open vessel, evaporate on a steam bath to dr yness, 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.