graph. Calculate the percentage of sodium taken by the formula:

$$A / W$$

in which *A* is the weight, in mg, of sodium found per L and *W* is the weight, in g, of Sodium Polystyrene Sulfonate taken. The sodium content is not less than 9.4% and not more than 11.5%, calculated on the anhydrous basis.

Potassium exchange capacity—

Potassium solution—Dissolve an accurately weighed quantity of potassium chloride in water to make a solution containing 5.00 mg of potassium per mL.

Sodium solution—Dissolve an accurately weighed quantity of sodium chloride in water to make a solution containing 4.00 mg of sodium per mL.

Standard graph—Identify five 1-liter volumetric flasks by the numbers *1*, *2*, *3*, *4*, and *5*. In that order pipet into the flasks 4, 3, 2, 1, and 0 mL, respectively, of *Sodium solution*, and in the same order 0, 1, 2, 3, and 4 mL, respectively, of *Potassium solution*. To each flask add 10 mL of low-sodium, low-potassium, nonionic surfactant solution (1 in 50), dilute with water to volume, and mix. Adjust the scale of a suitable flame spectrophotometer to 100 with solution from flask *5* at 766 nm. Determine the instrument readings with solutions from flasks *4*, *3*, *2*, and *1*. On ruled coordinate paper, plot the observed instrument readings as the ordinate, and the concentrations, in mg per liter, of potassium as the abscissa.

Procedure—Pipet 100 mL of *Potassium solution* into a glass-stoppered flask containing about 1.6 g of Sodium Polystyrene Sulfonate, accurately weighed, shake by mechanical means for 15 minutes, filter, and discard the first 20 mL of the filtrate. Pipet 5 mL of the filtrate into a 1-liter volumetric flask, add 10 mL of low-sodium, low-potassium, nonionic surfactant solution (1 in 50), dilute with water to volume, and mix. Observe the flame spectrophotometer readings of the exchanged solution concomitantly with those obtained for plotting the *Standard graph*, and determine the potassium concentration, in mg per liter, by interpolation from the *Standard graph*. Calculate the quantity, in mg per g, of potassium adsorbed on the resin taken by the formula:

$$(X - 20Y) / W$$

in which *X* is the weight, in mg, of potassium in 100 mL of *Potassium solution* before exchange; *Y* is the weight, in mg, of potassium per L as interpolated from the *Standard graph;* and *W* is the weight, in g, of Sodium Polystyrene Sulfonate taken, expressed on the anhydrous basis.

Sodium Polystyrene Sulfonate Suspension

» Sodium Polystyrene Sulfonate Suspension is a suspension of Sodium Polystyrene Sulfonate in an aqueous vehicle that may contain suitable suspending or stabilizing agents. It exchanges not less than 110 mg and not more than 135 mg of potassium for each g of the labeled amount of sodium polystyrene sulfonate.

Packaging and storage—Preserve in well-closed containers, protected from freezing and from excessive heat.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**Its total aerobic microbial count does not exceed 100 cfu per mL, its total combined molds and yeasts count does not exceed 100 cfu per mL, and it meets the requirements of the test for absence of *Pseudomonas aeruginosa*.

Sodium content—

Sodium solution and *Standard graph*—Prepare as directed in the test for *Sodium content* under *Sodium Polystyrene Sulfonate*.

Procedure—Transfer an accurately measured quantity of Suspension, freshly mixed and free from air bubbles, equivalent to about 1 g of sodium polystyrene sulfonate, to a suitable crucible, heat at 80° until dry, and ash the residue with a slight excess of sulfuric acid. Proceed as directed for *Procedure* in the test for *Sodium content* under *Sodium Polystyrene Sulfonate*, beginning with "Add 1 mL of nitric acid." Calculate the percentage of sodium taken by the formula:

$$A / L$$

in which *A* is the quantity, in mg, of sodium found per liter, and *L* is the quantity, in g, of sodium polystyrene sulfonate in the portion of Suspension taken, based on the labeled amount: the sodium content is not less than 9.4% and not more than 11.5%.

Potassium exchange capacity—

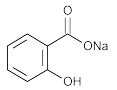
Potassium solution, Sodium solution, and *Standard graph*—Prepare as directed in the test for *Potassium exchange capacity* under *Sodium Polystyrene Sulfonate*.

Procedure—Transfer an accurately measured quantity of Suspension, freshly mixed and free from air bubbles, equivalent to about 1.6 g of sodium polystyrene sulfonate, to a suitable glass-stoppered flask, add 100.0 mL of *Potassium solution*, shake by mechanical means for 15 minutes, filter, and discard the first 20 mL of the filtrate. Proceed as directed for *Procedure* in the test for *Potassium exchange capacity* under *Sodium Polystyrene Sulfonate*, beginning with "Pipet 5 mL of the filtrate." Calculate the quantity, in mg, of potassium adsorbed on each g of the sodium polystyrene sulfonate taken by the formula:

$$(X - 20Y) / L$$

in which *X* is the quantity, in mg, of potassium in 100 mL of *Potassium solution* before exchange; *Y* is the quantity, in mg, of potassium per L as interpolated from the *Standard graph;* and *L* is the labeled quantity, in g, of sodium polystyrene sulfonate in the portion of Suspension taken.

Sodium Salicylate



$C_7H_5NaO_3$ 160.10
Benzoic acid, 2-hydroxy-, monosodium salt.
Monosodium salicylate [54-21-7].

» Sodium Salicylate contains not less than 99.5 percent and not more than 100.5 percent of $C_7H_5NaO_3$, calculated on the anhydrous basis.

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

Identification—A solution (1 in 20) responds to the tests for *Sodium* ⟨191⟩ and for *Salicylate* ⟨191⟩.

Water, *Method I* ⟨921⟩: not more than 0.5%.

Sulfite or thiosulfate—Add 1 mL of hydrochloric acid to a solution of 1.0 g in 20 mL of water, and filter the liquid: not more than 0.15 mL of 0.10 N iodine is required to produce a yellow color in the filtrate.

Heavy metals, *Method I* ⟨231⟩**—**Dissolve 2 g in 46 mL of water. Add, with constant stirring, 4 mL of 3 N hydrochloric acid, filter, and use 25 mL of the filtrate: the limit is 0.002%.

Assay—Transfer about 700 mg of Sodium Salicylate, accurately weighed, to a 250-mL beaker. Add 100 mL of glacial acetic acid, stir until the sample is completely dissolved, add crystal violet TS, and titrate with 0.1 N perchloric acid VS. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 16.01 mg of $C_7H_5NaO_3$.

Sodium Salicylate Tablets

» Sodium Salicylate Tablets contain not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_7H_5NaO_3$.

Packaging and storage—Preserve in well-closed containers.

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

Identification—

A: Digest a quantity of powdered Tablets, equivalent to about 1 g of sodium salicylate, with 20 mL of water, and filter: the filtrate responds to the flame test for *Sodium* ⟨191⟩ and to the tests for *Salicylate* ⟨191⟩.

B: To 10 mL of the filtrate obtained in *Identification* test *A* add a slight excess of 3 N hydrochloric acid, collect the precipitate on a filter, wash it with small portions of cold water until the last washing is free from chloride, and dry at about 105° for 1 hour: the salicylic acid so obtained melts between 158° and 161° (see *Melting Range or Temperature* ⟨741⟩).

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Procedure—Determine the amount of $C_7H_5NaO_3$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 230 nm, using filtered portions of the solution under test, diluted with water, if necessary, in comparison with a Standard solution having a known concentration of USP Sodium Salicylate RS in the same *Medium*.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_7H_5NaO_3$ is dissolved in 45 minutes.

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

Assay—Place not less than 20 Tablets in a 200-mL volumetric flask, add 100 mL of water, and allow to stand, with frequent agitation, until the tablets disintegrate completely. Dilute with water to volume, and mix. Filter through a dry filter into a dry flask, discarding the first 10 mL of the filtrate. Transfer an accurately measured volume of the subsequent filtrate, equivalent to about 500 mg of sodium salicylate, to a separator, and dilute with water, if necessary, to make about 25 mL. Add 75 mL of ether and 10 drops of bromophenol blue TS, and titrate with 0.1 N hydrochloric acid VS, mixing the water and ether layers by vigorous shaking until a permanent, pale green color is produced in the water layer. Draw off the water layer into a small flask, wash the ether layer once with 5 mL of water, and add this to the water layer. Add 20 mL of ether to the combined water solutions, and mix. Continue the titration with vigorous shaking until a permanent, pale green color is produced in the water layer. Each mL of 0.1 N hydrochloric acid is equivalent to 16.01 mg of $C_7H_5NaO_3$.

Sodium Sulfate

$Na_2SO_4 \cdot 10H_2O$ 322.20
Sulfuric acid disodium salt, decahydrate.
Disodium sulfate decahydrate [7727-73-3].
Anhydrous 142.04 [7757-82-6].

» Sodium Sulfate contains ten molecules of water of hydration, or is anhydrous. It contains not less than 99.0 percent of Na_2SO_4, calculated on the dried basis.

Packaging and storage—Preserve in tight containers, preferably at a temperature not exceeding 30°.

Labeling—Label it to indicate whether it is the decahydrate or is anhydrous.

Identification—A solution (1 in 20) responds to the tests for *Sodium* ⟨191⟩ and for *Sulfate* ⟨191⟩.

Acidity or alkalinity—To 10 mL of a solution, containing the equivalent of 1.0 g of $Na_2SO_4 \cdot 10H_2O$ in 20 mL of water, add 1 drop of bromothymol blue TS: not more than 0.50 mL of either 0.010 N hydrochloric acid or 0.010 N sodium hydroxide is required to change the color of the solution.

Loss on drying ⟨731⟩**—**Dry at 105° for 4 hours: the decahydrate loses between 51.0% and 57.0% of its weight, and the anhydrous form loses not more than 0.5% of its weight.

Chloride ⟨221⟩**—**A portion equivalent to 1.0 g of $Na_2SO_4 \cdot 10H_2O$ shows no more chloride than corresponds to 0.30 mL of 0.020 N hydrochloric acid (0.02%).

Heavy metals ⟨231⟩**—**Dissolve a portion containing the equivalent of 2.0 g of $Na_2SO_4 \cdot 10H_2O$ in 10 mL of water, add 2 mL of 0.1 N hydrochloric acid, then add water to make 25 mL: the limit is 0.001%.

Assay—Weigh accurately a portion of Sodium Sulfate, equivalent to about 400 mg of anhydrous sodium sulfate, dissolve in 200 mL of water, and add 1 mL of hydrochloric acid. Heat to boiling, and gradually add, in small portions and while constantly stirring, an excess of hot barium chloride TS (about 8 mL). Heat the mixture on a steam bath for 1 hour, collect the precipitate of barium sulfate on a retentive, ashless filter paper, wash until free from chloride when tested with silver nitrate TS, and place the filter into a suitable tared crucible. Carefully burn away the paper, and ignite at 800 ± 25° to constant weight. The weight of the barium sulfate so obtained, multiplied by 0.6086, represents its equivalent of Na_2SO_4.

Sodium Sulfate Injection

» Sodium Sulfate Injection is a sterile, concentrated solution of Sodium Sulfate in Water for Injection, which upon dilution is suitable for parenteral use. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $Na_2SO_4 \cdot 10H_2O$.

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

Labeling—Label it to indicate that it is to be diluted before injection to render it isotonic (3.89% of $Na_2SO_4 \cdot 10H_2O$).

Identification—It responds to the tests for *Sodium* ⟨191⟩ and for *Sulfate* ⟨191⟩.

Pyrogen—When diluted with water for injection to contain 3.89% of $Na_2SO_4 \cdot 10H_2O$, it meets the requirements of the *Pyrogen Test* ⟨151⟩.

pH ⟨791⟩: between 5.0 and 6.5.

Other requirements—It meets the requirements under *Injections* ⟨1⟩.

Assay—Transfer an accurately measured volume of Injection, equivalent to about 400 mg of sodium sulfate ($Na_2SO_4 \cdot 10H_2O$), to a suitable vessel. Dilute if necessary, to 200 mL, and proceed as directed in the *Assay* under *Sodium Sulfate*, beginning with "add 1 mL of hydrochloric acid." The weight of the barium sulfate so obtained, multiplied by 1.3804, represents its equivalent of $Na_2SO_4 \cdot 10H_2O$.