phosphate buffer as the blank. Calculate the quantity, in mg, of $C_7H_7KO_5S$ in the Potassium Guaiacolsulfonate taken by the formula:

$$5C(A_U / A_S)$$

in which C is the concentration, in µg per mL, calculated on the anhydrous basis, of USP Potassium Guaiacolsulfonate RS in the Standard solution, and A_U and A_S are the absorbances of the preparation under assay and the Standard solution, respectively.

Potassium Iodide

KI 166.00
Potassium iodide [7681-11-0].

DEFINITION
Potassium Iodide contains NLT 99.0% and NMT 101.5% of KI, calculated on the dried basis.

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Potassium* ⟨**191**⟩**:** Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL,** *Iodide* ⟨**191**⟩**:** Meets the requirements

ASSAY
- **PROCEDURE**
  Sample solution: Dissolve 500 mg of Potassium Iodide in 10 mL of water.
  Analysis: Add 35 mL of hydrochloric acid to the *Sample solution*, and titrate with 0.05 M potassium iodate VS until the dark brown solution that is produced becomes pale brown. Add 2–3 drops of amaranth TS, and continue the titration slowly until the red color just changes to yellow. Each mL of 0.05 M potassium iodate is equivalent to 16.60 mg of KI.
  Acceptance criteria: 99.0%–101.5% on the dried basis

IMPURITIES
- **HEAVY METALS** ⟨**231**⟩
  Sample solution: Dissolve 2.0 g in 25 mL of water.
  Acceptance criteria: NMT 10 ppm
- **IODATE**
  Iodate solution: Dilute 1 mL of potassium iodate solution (1 in 2500) with water to 100 mL.
  Standard solution: Dissolve 100 mg of Potassium Iodide in ammonia- and carbon dioxide-free water, and add 1 mL of *Iodate solution* to obtain 10 mL of solution. Transfer to a color-comparison tube, add 1 mL of starch TS and 0.25 mL of 1.0 N sulfuric acid, and mix.
  Sample solution: Dissolve 1.1 g in sufficient ammonia- and carbon dioxide-free water to obtain 10 mL of solution. Transfer to a color-comparison tube, add 1 mL of starch TS and 0.25 mL of 1.0 N sulfuric acid, and mix.
  Acceptance criteria: Any color produced in the *Sample solution* does not exceed that produced in the *Standard solution* (NMT 4 µg/g).
- **LIMIT OF NITRATE, NITRITE, AND AMMONIA**
  Sample solution: Dissolve 1 g in 5 mL of water.
  Analysis: To the *Sample solution* contained in a test tube of 40-mL capacity add 5 mL of 1 N sodium hydroxide and 200 mg of aluminum wire. Insert a pledget of purified cotton in the upper portion of the test tube, and place a piece of moistened red litmus paper over the mouth of the tube. Heat the test tube and its contents in a steam bath for 15 min.
  Acceptance criteria: No blue coloration of the paper is discernible.
- **THIOSULFATE AND BARIUM**
  Sample solution: Dissolve 0.5 g in 10 mL of ammonia- and carbon dioxide-free water.
  Analysis: Add 2 drops of 2 N sulfuric acid.
  Acceptance criteria: No turbidity develops within 1 min.

SPECIFIC TESTS
- **ALKALINITY**
  Sample solution: Dissolve 1.0 g of Potassium Iodide in 10 mL of water.
  Analysis: Add 0.1 mL of 0.1 N sulfuric acid and 1 drop of phenolphthalein TS to the *Sample solution*.
  Acceptance criteria: No color is produced.
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample at 105° for 4 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

Potassium Iodide Oral Solution

» Potassium Iodide Oral Solution contains not less than 94.0 percent and not more than 106.0 percent of the labeled amount of KI.
NOTE—If Potassium Iodide Oral Solution is not to be used within a short time, add 0.5 mg of sodium thiosulfate for each g of KI. Products that have data to demonstrate acceptable stability without the addition of thiosulfate are exempt from this requirement. Crystals of potassium iodide may form in Potassium Iodide Oral Solution under normal conditions of storage, especially if refrigerated.

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

Identification—It responds to the tests for *Potassium* ⟨191⟩ and for *Iodide* ⟨191⟩.

Uniformity of dosage units ⟨905⟩**—**

FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩**—**

FOR ORAL SOLUTION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

Assay—Dilute an accurately measured volume of Oral Solution with water to obtain a solution containing about 50 mg of potassium iodide per mL. To 10.0 mL of this solution, in a 150-mL beaker, add about 40 mL of water, 25 mL of alcohol, and 1.0 mL of 1 N nitric acid. Titrate with 0.1 N silver nitrate VS, determining the endpoint potentiometrically, using silver-calomel electrodes and a salt bridge containing 4 percent agar in a saturated potassium nitrate solution. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N silver nitrate is equivalent to 16.60 mg of KI.

Potassium Iodide Tablets

» Potassium Iodide Tablets contain not less than 94.0 percent and not more than 106.0 percent of the labeled amount of KI for Tablets of 300 mg or more, and not less than 92.5 percent and not more than 107.5 percent for Tablets of less than 300 mg.

Packaging and storage—Preserve in tight containers.

Identification—A filtered solution of powdered Tablets responds to the tests for *Potassium* ⟨191⟩ and for *Iodide* ⟨191⟩.