Calculate the percentage of sodium in the portion of Potassium Acetate taken:

$$\text{Result} = (C/W) \times (V/F) \times 100$$

C = concentration of the *Sample solution*, determined from the graph (µg/mL)
W = weight of Potassium Acetate taken to prepare the *Sample solution* (g)
V = final volume of the *Sample solution*, taking into account any dilution necessary (mL)
F = conversion factor (1,000,000 µg/g)

Acceptance criteria: NMT 0.03%

SPECIFIC TESTS

- **pH** ⟨**791**⟩
  Sample solution: 50 mg/mL
  Acceptance criteria: 7.5–8.5
- **Loss on Drying** ⟨**731**⟩**:** Dry a sample at 150° for 2 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.

Potassium Acetate Injection

» Potassium Acetate Injection is a sterile solution of Potassium Acetate in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_2H_3KO_2$.

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

Labeling—The label states the potassium acetate content in terms of weight and of milliequivalents in a given volume. Label the Injection to indicate that it is to be diluted to appropriate strength with water or other suitable fluid prior to administration. The label states also the total osmolar concentration in mOsmol per L. Where the contents are less than 100 mL, or where the label states that the Injection is not for direct injection but is to be diluted before use, the label alternatively may state the total osmolar concentration in mOsmol per mL.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS

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

Bacterial endotoxins ⟨85⟩**—**It contains not more than 8.80 USP Endotoxin Units per mEq.

pH ⟨791⟩: between 5.5 and 8.0, when diluted with water to 1.0% of potassium acetate.

Particulate matter ⟨788⟩: meets the requirements under small-volume injections.

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

Assay—

Potassium stock solution—Dissolve 190.7 mg of potassium chloride, previously dried at 105° for 2 hours, in water. Transfer to a 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 100.0 mL of this solution to a 1000-mL volumetric flask, dilute with water to volume, and mix. This solution contains 10 µg of potassium (equivalent to 19.07 µg of potassium chloride) per mL.

Standard preparations—To separate 100-mL volumetric flasks transfer 10.0, 15.0, and 20.0 mL, respectively, of *Potassium stock solution*. To each flask add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix. The *Standard preparations* contain, respectively, 1.0, 1.5, and 2.0 µg of potassium per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 2 g of potassium acetate, to a 500-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the solution to a 250-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparations* and the *Assay preparation* at the potassium emission line of 766.5 nm, with a suitable atomic absorption spectrophotometer (see *Spectrophotometry and Light-scattering* ⟨851⟩) equipped with a potassium hollow-cathode lamp and an air–acetylene flame, using water as the blank. Plot the absorbance of the *Standard preparation* versus concentration, in µg per mL, of potassium, and draw the straight line best fitting the three plotted points. From the graph so obtained, determine the concentration, in µg per mL, of potassium in the *Assay preparation*. Calculate the quantity, in mg, of $C_2H_3KO_2$ in the portion of Injection taken by the formula:

$$500C(2.510)$$

in which C is the concentration, in µg per mL, of potassium in the *Assay preparation*, and 2.510 is the ratio of the molecular weight of potassium acetate to the atomic weight of potassium.

Potassium Bicarbonate

$KHCO_3$ 100.12
Carbonic acid, monopotassium salt;
Monopotassium carbonate [298-14-6].

DEFINITION

Potassium Bicarbonate contains NLT 99.5% and NMT 101.5% of $KHCO_3$, calculated on the dried basis.

IDENTIFICATION

- **A. Identification Tests—General,** *Potassium* ⟨**191**⟩
  Sample solution: 100 mg/mL
  Acceptance criteria: Meets the requirements
- **B. Identification Tests—General,** *Bicarbonate* ⟨**191**⟩
  Sample solution: 100 mg/mL
  Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**
  Sample: 4 g
  Analysis: Dissolve the *Sample* in 100 mL of water, add methyl red TS, and titrate with 1 N hydrochloric acid VS. Add the acid slowly, with constant stirring, until the solution becomes faintly pink. Heat the solution to boiling, cool, and continue the titration until the pink color no longer fades after boiling. Each mL of 1 N hydrochloric acid is equivalent to 100.1 mg of $KHCO_3$.
  Acceptance criteria: 99.5%–101.5% on the dried basis

IMPURITIES

- **Heavy Metals,** *Method I* ⟨**231**⟩
  Sample solution: To 2 g add 5 mL of water and 8 mL of 3 N hydrochloric acid, heat to boiling, and maintain that temperature for 1 min. Add 1 drop of phenolphthalein TS and sufficient 6 N ammonium hydroxide, dropwise, to give the solution a faint pink color. Cool, add 2 mL of 1 N acetic acid, and then dilute with water to 25 mL.
  Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS

- **Loss on Drying** ⟨**731**⟩**:** Dry a sample over silica gel for 4 h: it loses NMT 0.3% of its weight.

• **NORMAL CARBONATE**

Sample: Grind 3.0 g of Potassium Bicarbonate with 25 mL of alcohol and 5 mL of water in a porcelain mortar.

Barium chloride solution: 12.216 mg/mL of barium chloride in alcohol and water (7:3), prepared by dissolving the barium chloride in water, then diluting with alcohol to final volume

Analysis: Add 3 drops of phenolphthalein TS to the *Sample*, and titrate slowly with *Barium chloride solution* until the suspension becomes colorless. Continue the grinding for 2 min, and if the color turns pink, continue the titration with *Barium chloride solution* to a colorless endpoint. Repeat the grinding for 2 min and the addition of *Barium chloride solution*, if necessary, until the suspension is colorless after 2 min of grinding. Each mL of the barium chloride solution is equivalent to 6.911 mg of K_2CO_3.

Acceptance criteria: NMT 2.5%

ADDITIONAL REQUIREMENTS

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

Potassium Bicarbonate Effervescent Tablets for Oral Solution

» Potassium Bicarbonate Effervescent Tablets for Oral Solution contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of K.

Packaging and storage—Preserve in tight containers, protected from excessive heat.

Labeling—The label states the potassium content in terms of weight and in terms of milliequivalents. Where the Tablets are packaged in individual pouches, the label instructs the user not to open until the time of use.

Identification—One Tablet dissolves in 100 mL of water with effervescence. The collected gas responds to the test for *Bicarbonate* ⟨191⟩, and the resulting solution responds to the test for *Potassium* ⟨191⟩.

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

Assay—

Potassium stock solution and *Standard preparations*—Prepare as directed in the *Assay* under *Potassium Chloride Oral Solution*.

Assay preparation—Transfer 10 Tablets to a 2000-mL volumetric flask, dissolve in 200 mL of water, swirl until effervescence ceases, dilute with water to volume, and mix. Filter, and quantitatively dilute an accurately measured volume of the filtrate with water to obtain a solution containing 30 µg of potassium per mL. Transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Potassium Chloride Oral Solution*. Calculate the quantity, in mg, of K in each Tablet taken by the formula:

$$L(C / D)$$

in which L is the labeled quantity, in mg, of potassium in each Tablet, C is the concentration, in µg per mL, of potassium in the *Assay preparation*, and D is the concentration, in µg per mL, of potassium in the *Assay preparation* on the basis of the labeled quantity in each Tablet and the extent of dilution.

Potassium Bicarbonate and Potassium Chloride for Effervescent Oral Solution

» Potassium Bicarbonate and Potassium Chloride for Effervescent Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of K and Cl.

Packaging and storage—Preserve in tight containers, protected from excessive heat.

Labeling—The label states the potassium and chloride contents in terms of weight and in terms of milliequivalents. Where packaged in individual pouches, the label instructs the user not to open until the time of use.

Identification—A 3-g portion dissolves in 100 mL of water with effervescence. The collected gas so obtained responds to the test for *Bicarbonate* ⟨191⟩, and the resulting solution responds to the tests for *Potassium* ⟨191⟩ and for *Chloride* ⟨191⟩.

Minimum fill ⟨755⟩**—**

FOR SOLID PACKAGED IN MULTIPLE-UNIT CONTAINERS*:* meets the requirements.

Uniformity of dosage units ⟨905⟩**—**

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

Assay for potassium—

Potassium stock solution and *Standard preparations*—Prepare as directed in the *Assay* under *Potassium Chloride Oral Solution*.

Assay preparation—Weigh and mix the contents of not less than 20 containers of Potassium Bicarbonate and Potassium Chloride for Effervescent Oral Solution. Transfer an accurately weighed portion of the powder, equivalent to about 6 g of potassium, to a 1000-mL volumetric flask, dissolve in about 200 mL of water, dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a second 1000-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of the resulting solution to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (1 in 5) and 1.0 mL of hydrochloric acid, dilute with water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Potassium Chloride Oral Solution.* Calculate the quantity, in mg, of K in the portion of Potassium Bicarbonate and Potassium Chloride for Effervescent Oral Solution taken by the formula:

$$400C$$

in which C is the concentration, in µg per mL, of potassium in the *Assay preparation.*

Assay for chloride—Weigh and mix the contents of not less than 20 containers of Potassium Bicarbonate and Potassium Chloride for Effervescent Oral Solution. Transfer a portion of the powder, equivalent to about 900 mg of chloride, to a 2000-mL volumetric flask. Add about 200 mL of water, swirl until effervescence ceases, dilute with water to volume, and mix. Transfer 25.0 mL of this solution to a 250-mL conical flask, add 50.0 mL of 0.1 N silver nitrate VS and 15 mL of nitric acid, and boil, with constant swirling, until the solution is colorless. Cool to room temperature, add water to make about 150 mL, then add 5 mL of ferric ammonium sulfate TS, and titrate the excess silver nitrate with 0.1 N ammonium thiocyanate VS to a permanent faint brown endpoint. Each mL of 0.1 N silver nitrate is equivalent to 3.545 mg of Cl.