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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—

Standard stock solution and *Standard solutions*—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 *Instrumental conditions* and *Analysis* in the *Assay* under *Potassium Chloride Oral Solution*, except use *Assay preparation* instead of *Sample 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.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
POTASSIUM BICARBONATE AND POTASSIUM CHLORIDE FOR EFFERVESCENT ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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