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Potassium Chloride, Potassium Bicarbonate, and Potassium Citrate Effervescent Tablets for Oral Solution

» Potassium Chloride, Potassium Bicarbonate, and Potassium Citrate Effervescent Tablets for Oral Solution contain 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 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 tests for *Potassium* ⟨191⟩, for *Chloride* ⟨191⟩, and for *Citrate* ⟨191⟩.

Uniformity of dosage units ⟨905⟩: meet the requirements for *Weight Variation*.

Assay for potassium—

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

Assay preparation—Transfer 10 Potassium Chloride, Potassium Bicarbonate, and Potassium Citrate Effervescent Tablets for Oral Solution 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 *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 potassium (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.

Assay for chloride—Transfer a number of Potassium Chloride, Potassium Bicarbonate, and Potassium Citrate Effervescent Tablets for Oral Solution, 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 supernatant is colorless. Cool to room temperature, add sufficient water to make a volume of about 150 mL, 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. Calculate the quantity, in mg, of chloride (Cl) in each Tablet by dividing the total amount of chloride in the Tablets taken by the number of Tablets taken.

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

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

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