Gold chloride solution—Dissolve a quantity of gold chloride in water to obtain a 0.5% (w/v) solution.

Blank—Use water.

Bromide standard stock solution—Dissolve an accurately weighed quantity of USP Sodium Bromide RS in water to obtain a solution having a known concentration equivalent to about 20 mg of bromide per mL.

Standard preparations—Prepare four *Standard preparation* solutions of known concentrations of about 2.0 mg of bromide per mL, 1.0 mg of bromide per mL, 0.5 mg of bromide per mL, and 0.25 mg of bromide per mL by quantitatively diluting the *Bromide standard stock solution* with the appropriate volumes of water.

Assay preparation—Dilute Oral Solution, Veterinary quantitatively with water (1:99).

Procedure (see *Spectrophotometry and Light Scattering* ⟨851⟩)—To 750-µL aliquots each of *Blank,* the four *Standard preparations,* and the *Assay preparation* add 500 µL of *TCA solution* and 250 µL of *Gold chloride solution*. Mix on a vortex mixer, and immediately read the absorbance at 440 nm. Generate a standard curve of absorbance versus bromide concentration, correcting for the blank, and calculate the regression line and the regression coefficient. The test is considered valid if the square of the correlation coefficient of the regression curve (r^2) is not less than 0.99. Calculate the concentration, in mg per mL, of bromide (Br^-) in the portion of Oral Solution, Veterinary taken by the formula:

$$100C$$

in which *C* is the concentration, in mg per mL, of bromide in the *Assay preparation* as calculated from the regression line.

Potassium Carbonate

K_2CO_3 (anhydrous) 138.21

$K_2CO_3 \cdot 1\frac{1}{2}H_2O$ 165.23

Carbonic acid, dipotassium salt;
Dipotassium carbonate [584-08-7].

DEFINITION
Potassium Carbonate contains NLT 99.5% and NMT 100.5% of K_2CO_3, calculated on the dried basis.

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

ASSAY
- **PROCEDURE**
  Sample: Dried potassium carbonate obtained in the test for *Loss on Drying*
  Analysis: Transfer the *Sample* to a flask with the aid of 150 mL of water, and add 4 drops of methyl orange TS. Titrate with 1 N hydrochloric acid VS. Each mL of 1 N hydrochloric acid is equivalent to 69.11 mg of K_2CO_3.
  Acceptance criteria: 99.5%–100.5% on the dried basis

IMPURITIES
- **HEAVY METALS** ⟨**231**⟩
  Analysis: Dissolve 4.0 g in 10 mL of water. Add 15 mL of 3 N hydrochloric acid, and heat to boiling. Add 1 drop of phenolphthalein TS, and neutralize with 1 N sodium hydroxide until the solution is faintly pink in color. Cool, and dilute with water to 25 mL.
  Acceptance criteria: NMT 5 ppm

SPECIFIC TESTS
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample at 180° for 4 h: it loses NMT 0.5% of its weight.
- **INSOLUBLE SUBSTANCES**
  Sample solution: 1 g in 20 mL of water
  Acceptance criteria: The solution is complete, clear, and colorless.

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

Potassium Chloride

KCl 74.55

Potassium chloride [7447-40-7].

DEFINITION
Potassium Chloride contains NLT 99.0% and NMT 100.5% of KCl, calculated on the dried basis.

IDENTIFICATION
- **A. IDENTIFICATION TESTS—GENERAL,** *Potassium* ⟨**191**⟩
  Sample solution: 50 mg/mL
  Acceptance criteria: Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL,** *Chloride* ⟨**191**⟩
  Sample solution: 50 mg/mL
  Acceptance criteria: Meets the requirements

ASSAY
- **PROCEDURE**
  Sample: 200 mg
  Analysis: Dissolve the *Sample* in 10 mL of water. Add 10 mL of glacial acetic acid, 75 mL of methanol, and 3 drops of eosin Y TS. Titrate, with shaking, with 0.1 N silver nitrate VS to a pink endpoint. Each mL of 0.1 N silver nitrate is equivalent to 7.455 mg of KCl.
  Acceptance criteria: 99.0%–100.5% on the dried basis

IMPURITIES
- **ALUMINUM** ⟨**206**⟩ (where it is labeled as intended for use in hemodialysis)**:** Proceed as directed, using 2.0 g of Potassium Chloride to prepare the *Test preparation*.
  Acceptance criteria: NMT 1 ppm
- **SODIUM**
  Sample solution: 50 mg/mL
  Acceptance criteria: *Sample solution* tested on a platinum wire does not impart a pronounced yellow color to a nonluminous flame.
- **IODIDE**
  Standard stock solution: 1.64 mg/mL of potassium iodide in water
  Standard solution: Dilute 1.0 mL of *Standard stock solution* with water to 25 mL. Dilute 2.0 mL of this solution with water to 8 mL. Add 1 mL each of chloroform and diluted hydrochloric acid, then add 2 drops of a chloramine T solution (0.1 in 100), and shake gently.
  Sample solution: Dissolve 2 g of Potassium Chloride in 8 mL of water. Add 1 mL each of chloroform and diluted hydrochloric acid, then add 2 drops of a chloramine T solution (0.1 in 100), and shake gently.
  Acceptance criteria: The violet color of the chloroform layer is not darker than that of a concomitantly prepared *Standard solution* (NMT 0.005%).
- **BROMIDE**
  Standard stock solution: 1.28 mg/mL of sodium bromide in water
  Standard solution: Dilute 2.0 mL of *Standard stock solution* with water to 8 mL. Add 1 mL each of chloroform and diluted hydrochloric acid, then add 5 drops of a chloramine T solution (1 in 100), and shake gently.

Sample solution: Dissolve 2 g of Potassium Chloride in 8 mL of water. Add 1 mL each of chloroform and diluted hydrochloric acid, then add 5 drops of a chloramine T solution (1 in 100), and shake gently.
Acceptance criteria: The brown color of the chloroform layer is not darker than that of a concomitantly prepared *Standard solution* (NMT 0.1%).

- **CALCIUM AND MAGNESIUM**
Sample solution: 10 mg/mL in water
Analysis: To 20 mL of *Sample solution* add 2 mL each of 6 N ammonium hydroxide, ammonium oxalate TS, and dibasic sodium phosphate TS.
Acceptance criteria: No turbidity is produced within 5 min.
- **HEAVY METALS** ⟨**231**⟩
Sample solution: 2.0 g in 25 mL of water
Acceptance criteria: NMT 10 ppm

SPECIFIC TESTS
- **ACIDITY OR ALKALINITY:** To a solution of 5.0 g in 50 mL of carbon dioxide-free water add 3 drops of phenolphthalein TS: no pink color is produced. Then add 0.30 mL of 0.020 N sodium hydroxide: a pink color is produced.
- **LOSS ON DRYING** ⟨**731**⟩**:** Dry a sample at 105° for 2 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Where Potassium Chloride is intended for use in hemodialysis, it is so labeled.

Potassium Chloride Extended-Release Capsules

» Potassium Chloride Extended-Release Capsules contain not less than 90.0 percent and not more than 110.0 percent of the labeled amount of KCl.

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

Identification—A portion of the filtrate obtained as directed under *Assay* in the *Assay* responds to the tests for *Potassium* ⟨191⟩ and for *Chloride* ⟨191⟩.

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 2 hours.

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

Procedure—Filter the solution under test, and dilute quantitatively with *Dissolution Medium* to obtain a test solution containing about 60 µg of potassium chloride per mL. Add 5.0 mL of the test 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, mix, and proceed as directed for *Procedure* in the *Assay* under *Potassium Chloride Oral Solution*. Calculate the quantity, in mg, of KCl dissolved by the formula:

$$(900F)(1.907C)$$

in which F is the extent of dilution of the solution under test, and the other terms are as defined therein.

Tolerances—Not more than 35% *(Q)* of the labeled amount of KCl is dissolved in 2 hours. The requirements are met if the quantities dissolved from the Capsules tested conform to the accompanying acceptance table instead of the table shown under *Dissolution* ⟨711⟩.

Acceptance Table

Stage	Number Tested	Acceptance Criteria
S_1	6	Each unit is within the range $Q \pm 30\%$.
S_2	6	Average of 12 units ($S_1 + S_2$) is within the range between $Q - 30\%$ and $Q + 35\%$, and no unit is outside the range $Q \pm 40\%$.
S_3	12	Average of 24 units ($S_1 + S_2 + S_3$) is within the range between $Q - 30\%$ and $Q + 35\%$, and not more than 2 units are outside the range $Q \pm 40\%$.

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—Place not less than 20 Capsules in a suitable container with 400 mL of water, heat to boiling, and boil for 20 minutes. Allow to cool, transfer the solution to a 1000-mL volumetric flask, dilute with water to volume, and mix. Filter, discarding the first 20 mL of the filtrate. Transfer an accurately measured volume of the subsequent filtrate, equivalent to about 60 mg of potassium chloride, to a 1000-mL volumetric flask, dilute with water to volume, and mix. (Retain a portion of the filtrate for use in the *Identification* test.) 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 KCl in each Capsule taken by the formula:

$$(TC / D)(1.907)$$

in which T is the labeled quantity, in mg, of potassium chloride in each Capsule, D is the concentration, in µg per mL, of potassium chloride in the *Assay preparation*, based on the labeled quantity per Capsule and the extent of dilution, and the other terms are as defined therein.

Potassium Chloride for Injection Concentrate

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

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 chloride content in terms of weight and of milliequivalents in a given volume. Label the Concentrate to indicate that it is to be diluted to appropriate strength with water or other suitable fluid prior to administration. Immediately following the name, the label bears the boxed warning:

Concentrate Must be Diluted Before Use

This warning is not required when the liquid preparation is in a *Pharmacy bulk package* and the label thereon states prominently "Pharmacy Bulk Package—Not for direct infusion."

The cap of the container and the overseal of the cap must be black, and both bear the words: "Must Be Diluted" in readily legible type, in a color that stands out from its background OR