**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°C.

**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:

\[
(900F)(1.907)C
\]

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).

**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:

\[(\text{TC} / \text{D})(1.907)\]

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
the overseal may be of a clear plastic material through which the black cap is visible and the printing is readily legible.

When the nature of the container-closure system prevents compliance, the design shall follow the intent of this requirement as closely as possible, the black color being used beneath the words: “Must be Diluted,” which are so placed that words are readily visible as the contents of the container are being removed. Ampuls shall be identified by a black band or a series of black bands above the constriction. The label states also the total osmolar concentration in mOs/m per L. Where the contents are less than 100 mL, the label alternatively may state the total osmolar concentration in mOs/m per mL.

**USP Reference standards (11)—**

**USP Endotoxin RS**

**Identification**—It responds to the tests for Potassium (191) and for Chloride (191).

**Bacterial endotoxins** (85): It contains not more than 8.80 USP Endotoxin Units per mL.

**pH** (791): between 4.0 and 8.0.

**Particulate matter** (788): meets the requirements under small-volume injections.

**Other requirements**—It meets the requirements under Injections (1).

**Assay**—

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

Assay preparation—Transfer an accurately measured volume of Concentrate, equivalent to about 600 mg of potassium chloride, to a 500-mL volumetric flask, dilute with water to volume, and mix. Proceed as directed for Assay preparation in the Assay under Potassium Chloride Oral Solution, beginning with “Transfer 5.0 mL of the solution to a 100-mL volumetric flask.”

Procedure—Proceed as directed for Procedure in the Assay under Potassium Chloride Oral Solution. Calculate the quantity, in mg, of KCl in the portion of Concentrate taken by the formula:

\[ 200C(1.907) \]

in which the terms are as defined therein.

## Potassium Chloride Oral Solution

**DEFINITION**

Potassium Chloride Oral Solution contains NLT 95.0% and NMT 105.0% of the labeled amount of potassium chloride (KCl). It may contain alcohol.

**IDENTIFICATION**

- **A. IDENTIFICATION TESTS—GENERAL, Potassium (191)**
  - **Sample solution:** Carefully evaporate 5 mL to dryness, and ignite the residue at dull-red heat to remove all organic matter. Cool, dissolve the residue in 10 mL of water, and filter. Acceptance criteria: Meets the requirements

- **B. IDENTIFICATION TESTS—GENERAL, Chloride (191)**
  - **Sample solution:** Carefully evaporate 5 mL to dryness, and ignite the residue at dull-red heat to remove all organic matter. Cool, dissolve the residue in 10 mL of water, and filter. Acceptance criteria: Meets the requirements

**ASSAY**

- **PROCEDURE**
  - **Standard stock solution:** 19.07 µg/mL of potassium chloride, previously dried at 105°C for 2 h, in water. This solution contains 10 µg/mL of potassium.
  - **Standard solutions:** To separate 100-mL volumetric flasks transfer 10.0, 15.0, and 20.0 mL, respectively, of Standard stock solution. To each flask add 2.0 mL of sodium chloride solution (200 mg/mL) and 1.0 mL of hydrochloric acid, and dilute with water to volume. The Standard solutions contain, respectively, 1.0, 1.5, and 2.0 µg/mL of potassium.
  - **Sample stock solution:** Transfer a volume of Oral Solution, equivalent to 600 mg of potassium chloride, to a 500-mL volumetric flask, and dilute with water to volume. Transfer 5.0 mL of the solution to a 100-mL volumetric flask, and dilute with water to volume.
  - **Sample solution:** Transfer 5.0 mL of Sample stock solution to a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (200 mg/mL) and 1.0 mL of hydrochloric acid, and dilute with water to volume.

**SPECIFIC TESTS**

- **ALCOHOL CONTENT, Method II (611) (if present):** NLT 90.0% and NMT 115.0% of the labeled amount, the labeled amount being NMT 7.5% of CH₃OH, acetone being used as the internal standard

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers.

## Potassium Chloride for Oral Solution

« Potassium Chloride for Oral Solution is a dry mixture of Potassium Chloride and one or more suitable colors, diluents, and flavors. It contains 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.

**Labeling**—The label states the Potassium Chloride (KCl) content in terms of weight and in terms of milliequivalents.

**Identification**—Ignite about 200 mg at a temperature not above 600°C; in order to remove all organic matter, cool, dissolve the residue in 10 mL of water, and filter; the filtrate 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.