

Status: Currently Official on 16-Feb-2025

Official Date: Official as of 01-May-2018

Document Type: USP Monographs

DocId: GUID-89EC8ADF-4B89-460A-A788-AF30E06A17FC_3_en-US

DOI: https://doi.org/10.31003/USPNF_M67360_03_01

DOI Ref: 8k3k9

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Do not distribute

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 over seal 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 over seal 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 mOsmol per L. Where the contents are less than 100 mL, the label alternatively may state the total osmolar concentration in mOsmol per mL.

Identification—It responds to the tests for [Potassium \(191\)](#) and for [Chloride \(191\)](#).

BACTERIAL ENDOTOXINS TEST (85): It contains not more than 8.80 USP Endotoxin Units per mEq.

pH (791): between 4.0 and 8.0.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements under small-volume injections.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products \(1\)](#).

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.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
POTASSIUM CHLORIDE FOR INJECTION CONCENTRATE	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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: [GUID-89EC8ADF-4B89-460A-A788-AF30E06A17FC_3_en-US](#)

Previous DocID: [GUID-89EC8ADF-4B89-460A-A788-AF30E06A17FC_1_en-US](#)

DOI: https://doi.org/10.31003/USPNF_M67360_03_01

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