

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Jan-2021
 Document Type: USP Monographs
 DocId: GUID-5590B24F-3EE7-4424-BE49-9117505BA8D3_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M67345_03_01
 DOI Ref: dqb4d

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Potassium Chloride Extended-Release Capsules

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DEFINITION

Potassium Chloride Extended-Release Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of potassium chloride (KCl).

IDENTIFICATION

• A. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Potassium](#)

Sample solution: A portion of the filtrate, obtained as directed for *Sample stock solution* in the Assay

Acceptance criteria: Meet the requirements

• B. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)

Sample solution: A portion of the filtrate, obtained as directed for *Sample stock solution* in the Assay

Acceptance criteria: Meet the requirements

ASSAY

• PROCEDURE

Standard stock solution: 19.07 µg/mL of [potassium chloride](#), previously dried at 105° 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: Place NLT 20 Capsules in a suitable container with 400 mL of [water](#), heat to boiling, and boil for 20 min. Allow to cool, transfer the solution to a 1000-mL volumetric flask, and dilute with [water](#) to volume. Filter, discarding the first 20 mL of the filtrate. Transfer a measured volume of the subsequent filtrate, equivalent to 60 mg of potassium chloride, to a 1000-mL volumetric flask, and dilute with [water](#) to volume. [NOTE—Retain a portion of the filtrate for use in the *Identification* tests.]

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.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Potassium emission line at 766.5 nm

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Blank: [Water](#)

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Blank*

Plot the absorbance of the *Standard solutions* versus the concentration of potassium, in µg/mL, and draw the straight line best fitting the three plotted points. From the graph, determine the concentration of potassium in the *Sample solution* (µg/mL).

Calculate the percentage of the labeled amount of potassium chloride (KCl) in each Capsule taken:

$$\text{Result} = (C/C_U) \times (M_r/A) \times 100$$

C = concentration of potassium in the *Sample solution* as determined in this test (µg/mL)

C_U = concentration of potassium chloride in the *Sample solution* (µg/mL)

M_r = molecular weight of potassium chloride, 74.55

A_r = atomic weight of potassium, 39.10

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

Test 1

Medium: [Water](#); 900 mL

Apparatus 1: 100 rpm

Time: 2 h

Standard stock solution: 19.07 µg/mL of [potassium chloride](#), previously dried at 105° 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: Filter the solution under test, and dilute quantitatively with *Medium* to obtain a solution containing 60 µg/mL of potassium chloride.

Sample solution: Add 5.0 mL of the *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.

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: Potassium emission line at 766.5 nm

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Blank: [Water](#)

Analysis

Samples: *Standard solutions*, *Sample solution*, and *Blank*

Plot the absorbance of the *Standard solutions* versus the concentration of potassium, in µg/mL, and draw the straight line best fitting the three plotted points. From the graph, determine the concentration of potassium in the *Sample solution* (µg/mL).

Calculate the percentage of the labeled amount of potassium chloride (KCl) dissolved:

$$\text{Result} = [C \times D \times (V/L)] \times (M_r/A_r) \times 100$$

C = concentration of potassium in the *Sample solution* as determined in this test (µg/mL)

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

L = labeled amount of potassium chloride (µg/Capsule)

M_r = molecular weight of potassium chloride, 74.55

A_r = atomic weight of potassium, 39.10

Tolerances: NMT 35% (Q) of the labeled amount of potassium chloride (KCl) is dissolved in 2 h. The requirements are met if the quantities dissolved from the Capsules tested conform to [Table 1](#) instead of to the table shown in [Dissolution \(711\)](#).

Table 1

Stage	Number Tested	Acceptance Criteria
S_1	6	Each unit is within the range $Q \pm 30\%$.