

## Potassium Chloride Extended-Release Tablets

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<b>Expert Committee</b>	Chemical Medicines Monographs 5
<b>Reason for Revision</b>	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 5 Expert Committee has revised the Potassium Chloride Extended-Release Tablets monograph. The purpose for the revision is to add a new *Dissolution Test 7* to accommodate FDA-approved drug products with different dissolution conditions and tolerances than the existing dissolution tests.

The Potassium Chloride Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Ren-Hwa Yeh, Senior Scientific Liaison (301-998-6818 or [rhy@usp.org](mailto:rhy@usp.org)).

## Potassium Chloride Extended-Release Tablets

### DEFINITION

Potassium Chloride Extended-Release Tablets 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 the designated *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 the designated *Sample stock solution* in the Assay

**Acceptance criteria:** Meet the requirements

### ASSAY

• **PROCEDURE**

[NOTE—If necessary, first score nonsugar-coated Tablets. Retain a portion of the filtrate of either *Sample stock solution 1* or *Sample stock solution 2* for use in *Identification A* and *B*.]

**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 (1 in 5) and 1.0 mL of [hydrochloric acid](#), and dilute with [water](#) to volume. The *Standard solutions* contain 1.0, 1.5, and 2.0 µg/mL of potassium, respectively.

#### Sample preparation 1

**Sample stock solution 1:** Nominally 0.06 mg/mL of potassium chloride prepared as follows. Place NLT 20 Tablets 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 and discard 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.

**Sample solution 1:** Nominally 3 µg/mL of potassium chloride prepared as follows. Transfer 5.0 mL of *Sample stock solution 1* to a 100-mL volumetric flask, add 2.0 mL of [sodium chloride](#) solution (1 in 5) and 1.0 mL of [hydrochloric acid](#), and dilute with [water](#) to volume.

#### Sample preparation 2 (for formulations containing crystals coated with hydrophobic polymers)

**Sample stock solution 2:** Nominally 0.06 mg/mL of potassium chloride prepared as follows. Place NLT 20 Tablets in a 2000-mL volumetric flask. Add 1200 mL of a mixture of [acetonitrile](#) and [water](#) (1:1), and shake by mechanical means, or stir using a magnetic bar for 90 min. Dilute with the mixture of [acetonitrile](#) and [water](#) (1:1) to volume. Allow to stand for 90 min. Pass through a filter of 0.2-µm pore size. Transfer a measured volume of the filtrate, and quantitatively dilute with water to obtain a solution with a concentration of 0.06 mg/mL. [NOTE—Alternatively, *Sample stock solution 2* can be prepared by the following procedure. Nominally 0.15 mg/mL of potassium chloride from NLT 20 finely powdered Tablets, prepared as follows. Transfer an appropriate amount of the powder, equivalent to about 5–6 Tablets, to a suitable volumetric flask, add 10% of the final flask volume of [acetone](#), and sonicate for 45 min with intermittent shaking. Add 80% of the final flask volume of [water](#) and sonicate for 45 min with intermittent shaking. Cool to room temperature and dilute with [water](#) to volume. Centrifuge a portion of

the solution at 5000 rpm for 10 min. Transfer an appropriate amount of the supernatant to a 100-mL volumetric flask and dilute with [water](#) to volume to obtain a solution with a concentration of 0.15 mg/mL.]

**Sample solution 2:** Nominally 3 µg/mL of potassium chloride prepared as follows. Transfer an appropriate amount of *Sample stock solution 2* to a 100-mL volumetric flask, add 2.0 mL of [sodium chloride](#) solution (1 in 5) 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 1* or *Sample solution 2*, and *Blank*

Plot the absorbances 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 Tablet taken:

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

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

$C_U$  = nominal 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 2:** 50 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 (1 in 5) 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 with *Medium* to obtain a solution containing nominally 60 µg/mL of potassium chloride.

**Sample solution:** Transfer 5.0 mL of the *Sample stock 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](#), 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 absorbances of the *Standard solutions* versus the concentration of potassium, in  $\mu\text{g/mL}$ , and draw the straight line best fitting the three plotted points. From the graph, determine the concentration of potassium in the *Sample solution* ( $\mu\text{g/mL}$ ).

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 ( $\mu\text{g/mL}$ )

$D$  = dilution factor of the *Sample solution*

$V$  = volume of *Medium*, 900 mL

$L$  = labeled amount of potassium chloride ( $\mu\text{g/ Tablet}$ )

$M_r$  = 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 Tablets tested conform to [Table 1](#) instead of the table shown in [Dissolution \(711\)](#).

**Table 1**

Stage	Number Tested	Acceptance Criteria
$S_1$	6	Each unit is within the range $Q \pm 30\%$ .
$S_2$	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 NMT 2 units are outside the range $Q \pm 40\%$ .

**Test 2:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 2*.

**Standard stock solution and Standard solutions:** Prepare as directed in *Test 1*.

**Medium:** [Water](#); 900 mL

**Apparatus 2:** 50 rpm

**Times:** 1, 2, 4, and 8 h

**Sample stock solution:** Transfer 4.0 mL of the solution under test into either a 50-mL volumetric flask (for 750-mg Tablet) or a 100-mL volumetric flask (for 1500-mg Tablet), dilute with [water](#) to volume, and filter.

**Sample solution:** Transfer 4.0 mL of the *Sample stock 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](#), and dilute with [water](#) to volume.

**Blank 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](#), and dilute with [water](#) to volume.

**Instrumental conditions:** Proceed as directed in *Test 1*, except do not use the *Blank*.

### System suitability

**Samples:** *Standard solutions*

#### Suitability requirements

**Linearity:** Correlation coefficient NLT 0.99

**Relative standard deviation:** NMT 5.0% from 5 replicate analyses of the 1.5- $\mu\text{g/mL}$  *Standard solution*

### Analysis

**Samples:** 1.5- $\mu\text{g/mL}$  *Standard solution*, *Sample solution*, and *Blank solution*

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

$$\text{Result}_i = [(A_U/A_S) \times C_S \times D \times (V/L)] \times (M_r/A_r) \times 100$$

$A_U$  = absorbance of potassium in the *Sample solution*

$A_S$  = absorbance of potassium in the *Standard solution*

$C_S$  = concentration of potassium in the *Standard solution* ( $\mu\text{g/mL}$ )

$D$  = dilution factor of the *Sample solution*

$V$  = volume of *Medium*, 900 mL

$L$  = labeled amount of potassium chloride ( $\mu\text{g/Tablet}$ )

$M_r$  = molecular weight of potassium chloride, 74.55

$A_r$  = atomic weight of potassium, 39.10

**Tolerances:** See [Table 2](#).

**Table 2**

Time Point (i)	Time (h)	Amount Dissolved (%)	
		750 mg/Tablet	1500 mg/Tablet
1	1	10–30	5–25
2	2	30–50	25–45
3	4	60–80	55–75
4	8	NLT 80	NLT 85

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

**Test 3:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 3*.

**Medium:** [Water](#); 900 mL

**Apparatus 2:** 50 rpm

**Times:** 0.5, 2, 4, and 10 h

**Mobile phase:** 20 mM [methanesulfonic acid](#) in [water](#)

**Standard solution:** ( $L/900$ ) mg/mL of [USP Potassium Chloride RS](#) in [water](#), where  $L$  is the label claim of potassium chloride in mg/Tablet, prepared as follows. Transfer an appropriate quantity of [USP Potassium Chloride RS](#) to a suitable volumetric flask. Add 50% of the flask volume of [water](#) and sonicate to dissolve. Dilute with [water](#) to volume.

**Sample solution:** Pass a portion of the solution under test through a filter with a suitable pore size and use the filtrate.

**Chromatographic system**

(See [Chromatography \(621\), System Suitability.](#))

**Mode:** LC

**Detector:** Conductivity with suppression

**Column:** 4.0-mm × 25-cm; 8.5-μm packing [L106<sup>1</sup>](#)

**Column temperature:** 30°

**Flow rate:** 1.0 mL/min

**Injection volume:** 5 μL

**Run time:** NLT 2 times the retention time of potassium

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of potassium chloride (KCl) dissolved at each time point ( $i$ ):

$$\text{Result}_i = (r_U/r_S) \times C_S \times V \times (1/L) \times 100$$

$r_U$  = peak response of potassium from the *Sample solution*

$r_S$  = peak response of potassium from the *Standard solution*

$C_S$  = concentration of [USP Potassium Chloride RS](#) in the *Standard solution* (mg/mL)

$V$  = volume of *Medium*, 900 mL

$L$  = label claim of potassium chloride (mg/Tablet)

**Tolerances:** See [Table 3](#).

**Table 3**

Time Point ( $i$ )	Time (h)	Amount Dissolved (%)
1	0.5	15–35
2	2	40–60
3	4	60–80
4	10	NLT 80

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to [Dissolution \(711\), Acceptance Table 2](#).

**Test 4:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 4*.

**Standard stock solution and Instrumental conditions:** Proceed as directed in *Test 1*, except for the *Blank*.

**Medium:** [Water](#); 900 mL, degassed

**Apparatus 2:** 50 rpm

**Times:** 2, 4, and 8 h

**Sodium chloride solution:** 0.2 g/mL of [sodium chloride](#) in [water](#)

**Hydrochloric acid solution:** Dilute 100 mL of [hydrochloric acid](#) with 300 mL of [water](#).

**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* and 4.0 mL of *Hydrochloric acid solution*, and dilute with water to volume. The *Standard solutions* contain 1.0, 1.5, and 2.0 µg/mL of potassium, respectively.

**Sample stock solution:** Pass a portion of the solution under test through a filter with a suitable pore size and use the filtrate.

**Sample solution:** Transfer 1.0 mL of the *Sample stock solution* to a suitable volumetric flask and dilute with [water](#) if necessary. To the final dilution, add 2.0% flask volume of *Sodium chloride solution* and 4.0% flask volume of *Hydrochloric acid solution*, and dilute with [water](#) to volume.

**Blank:** To a suitable volumetric flask, add 2.0% flask volume of *Sodium chloride solution* and 4.0% flask volume of *Hydrochloric acid solution*, and dilute with [water](#) to volume.

#### System suitability

**Samples:** *Standard solutions*

#### Suitability requirements

**Linearity:** Correlation coefficient NLT 0.999

**Relative standard deviation:** NMT 1.5% from the absorbance responses of 5 replicate analyses of each *Standard solution*

**Analysis:** Proceed as directed in *Test 1*.

**Tolerances:** See [Table 4](#).

**Table 4**

Time Point (i)	Time (h)	Amount Dissolved (%)
1	2	22–42
2	4	44–64
3	8	NLT 80

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

**Test 5:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 5*.

**Medium:** [Water](#); 900 mL

**Apparatus 2:** 50 rpm

**Times:** 1, 2, and 8 h

**Dilute glacial acetic acid solution:** Dilute 25 mL of [glacial acetic acid](#) with 75 mL of [water](#).

**Saturated potassium sulfate solution:** Dissolve sufficient quantities of [potassium sulfate](#) in a suitable volume of [water](#) until undissolved particles appear in the solution.

**0.01 N silver nitrate solution:** Transfer 10 mL of [0.1 N silver nitrate VS](#) to a 100-mL volumetric flask and dilute with [water](#) to volume.

**Standard solution:** ( $L/900$ ) mg/mL of [potassium chloride](#), previously dried at 105° for 2 h, in [water](#), where  $L$  is the label claim in mg/Tablet. Pass the solution through a suitable filter.

**Sample solution:** Withdraw 10 mL of the solution under test at the specified time points and pass a suitable portion of the solution through a suitable filter. Replace each of the volumes withdrawn with an equal volume of the *Medium*.

**Blank:** *Medium*

#### Titrimetric system

(See [Titrimetry \(541\)](#).)

**Mode:** Direct titration

**Titrant:** 0.01 N silver nitrate solution

**Endpoint detection:** Potentiometric

#### System suitability

**Sample:** *Standard solution*

Transfer 5 mL of *Standard solution* into a titration vessel and add 25 mL of [water](#), 5 mL of *Dilute glacial acetic acid solution*, and 0.1 mL of *Saturated potassium sulfate solution* to the vessel. Titrate with *Titrant* and determine the endpoint potentiometrically.

#### Suitability requirements

**Relative standard deviation:** NMT 2.0% from 5 replicate analyses

#### Analysis

**Samples:** *Sample solution* and *Blank*

Transfer 5 mL of each solution into separate titration vessels and add 25 mL of [water](#), 5 mL of *Dilute glacial acetic acid solution*, and 0.1 mL of *Saturated potassium sulfate solution* to each vessel. Titrate with *Titrant* and determine the endpoint potentiometrically.

Calculate the concentration ( $C_i$ ) of potassium chloride (KCl) in the sample withdrawn from the vessel at each time point ( $i$ ):

$$\text{Result}_i = (V_U - V_B) \times N \times F \times (1/V_S)$$

$V_U$  = volume of *Titrant* used to titrate the *Sample solution*

$V_B$  = volume of *Titrant* used to titrate the *Blank*

$N$  = actual normality of *Titrant* (mEq/mL)

$F$  = equivalency factor, 74.55 mg/mEq

$V_S$  = volume of *Sample solution* used in the test, 5 mL

Calculate the percentage of the labeled amount of potassium chloride (KCl) dissolved at each time point ( $i$ ):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = [(C_2 \times V) + (C_1 \times V_W)] \times (1/L) \times 100$$

$$\text{Result}_3 = [(C_3 \times V) + (C_2 + C_1) \times V_W] \times (1/L) \times 100$$

$C_i$  = concentration of potassium chloride in the portion of sample withdrawn at the specific time point



$V$  = volume of *Medium*, 900 mL

$L$  = labeled amount of potassium chloride (mg/Tablet)

$V_w$  = volume of *Sample solution* withdrawn from vessel, 10 mL

**Tolerances:** See [Table 5](#).

**Table 5**

<b>Time Point (i)</b>	<b>Time (h)</b>	<b>Amount Dissolved (%)</b>
1	1	22–42
2	2	38–58
3	8	NLT 80

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

**Test 6:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 6*.

Use [water](#) with a resistivity of NLT 18 megohm-cm to prepare the solutions.

**Medium:** [Water](#); 900 mL

**Apparatus 2:** 50 rpm

**Times:** 1, 2, and 8 h

**0.1 M sulfuric acid solution:** Transfer 10 mL of [1 M sulfuric acid TS](#) into a 100-mL volumetric flask and dilute with [water](#) to volume.

**Mobile phase:** 0.01 M sulfuric acid in [water](#), from *0.1 M sulfuric acid solution*

**Standard solution:** 0.83 mg/mL of [USP Potassium Chloride RS](#) in [water](#)

**Sample solution:** Pass a portion of the solution under test through a filter with a suitable pore size and use the filtrate. Discard the first 2 mL of the filtrate.

**Blank solution:** *Medium*

#### **Chromatographic system**

(See [Chromatography \(621\)](#), [System Suitability](#).)

**Mode:** LC

**Detector:** Conductivity with suppression

#### **Columns**

**Guard:** 4.0-mm × 5-cm; 8.5- $\mu$ m packing [L106<sup>1</sup>](#)

**Analytical:** 4.0-mm × 25-cm; 8.5- $\mu$ m packing [L106<sup>1</sup>](#)

#### **Temperatures**

**Column:** 30°

**Cell:** 35°

**Flow rate:** 1.0 mL/min

**Injection volume:** 10  $\mu$ L

**Run time:** NLT 2 times the retention time of potassium

#### **System suitability**

**Sample:** *Standard solution*

#### **Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0%

## Analysis

### Samples: Standard solution and Sample solution

Calculate the concentration ( $C_i$ ) of potassium chloride (KCl) in the sample withdrawn from the vessel at each time point ( $i$ ):

$$C_i = (r_U/r_S) \times C_S$$

$r_U$  = peak response of potassium from the *Sample solution*

$r_S$  = peak response of potassium from the *Standard solution*

$C_S$  = concentration of [USP Potassium Chloride RS](#) in the *Standard solution* (mg/mL)

Calculate the percentage of the labeled amount of potassium chloride (KCl) dissolved at the specified time point ( $i$ ):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = \{[C_2 \times (V - V_S)] + (C_1 \times V_S)\} \times (1/L) \times 100$$

$$\text{Result}_3 = \{C_3 \times [(V - (2 \times V_S))] + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$C_i$  = concentration of potassium chloride in the portion of the sample withdrawn at the specified time point (mg/mL)

$V$  = volume of *Medium*, 900 mL

$L$  = label claim (mg/Tablet)

$V_S$  = volume of *Sample solution* withdrawn at each time point (mL)

**Tolerances:** See [Table 6](#).

**Table 6**

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	23–43
2	2	40–60
3	8	NLT 80

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to [Dissolution \(711\)](#), [Acceptance Table 2](#).

**▲Test 7:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 7*.

**Apparatus 2, Standard stock solution, Standard solutions, Sample solution, and Instrumental conditions:** Proceed as directed in *Test 1*.

**Medium:** [Water](#); 900 mL, degassed

**Times:** 1, 3, and 8 h

**Sample stock solution:** At each specified time point, withdraw 15 mL of the solution under test and pass a portion of the solution through a filter with a suitable pore size, discard the first 2 mL, and use the filtrate. Further dilute the filtrate with [water](#) as appropriate, ensuring the nominal concentration of

Sample solution is within the linearity range of the Standard solutions. [NOTE—Do not replace the Medium at the time of sampling.]

**System suitability**

**Samples:** Standard solutions

**Suitability requirement**

**Linearity:** Correlation coefficient NLT 0.995

**Recovery:** 90%–110%, back calculated from the 1.5 µg/mL Standard solution

**Analysis:** Proceed as directed in Test 1.

Plot the absorbances 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 at each time point (i):

$$\text{Result}_1 = C_1 \times D_1 \times V \times (1/L) \times (M_r/A_r) \times 100$$

$$\text{Result}_2 = \{[C_2 \times D_2 \times (V - V_S)] + (C_1 \times D_1 \times V_S)\} \times (1/L) \times (M_r/A_r) \times 100$$

$$\text{Result}_3 = (\{C_3 \times D_3 \times [V - (2 \times V_S)]\} + \{[(C_2 \times D_2) + (C_1 \times D_1)] \times V_S\}) \times (1/L) \times (M_r/A_r) \times 100$$

$C_i$  = concentration of potassium in the Sample solution at the specified time point (µg/mL)

$D_i$  = dilution factor of the Sample solution at the specified time point

$V$  = volume of Medium, 900 mL

$L$  = labeled amount of potassium chloride (µg/Tablet)

$M_r$  = molecular weight of potassium chloride, 74.55

$A_r$  = atomic weight of potassium, 39.10

$V_S$  = volume of Sample solution withdrawn at each time point, 15 mL

**Tolerances:** See Table 7.

**Table 7**

Time Point (i)	Time (h)	Amount Dissolved (%)
1	1	NMT 22
2	3	37–57
3	8	NLT 80

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to Dissolution (711), Acceptance Table 2. ▲ (RB 19-May-2020)

- **UNIFORMITY OF DOSAGE UNITS (905):** Meet the requirements

**ADDITIONAL REQUIREMENTS**

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store at a temperature not exceeding 30°.

- **LABELING:** The label states with which *Sample preparation* in the *Assay* the product complies only if *Sample preparation 1* is not used. When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

- **USP REFERENCE STANDARDS (11)**

[USP Potassium Chloride RS](#)

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<sup>1</sup> Weak cation-exchange resin consisting of ethylvinylbenzene, 55% cross-linked with divinylbenzene copolymer, 5–8  $\mu\text{m}$  diameter, macroporous particles having an average pore size of 100  $\text{\AA}$  units. Substrate is surface grafted with carboxylic acid and phosphonic acid functional groups. Capacity NLT 2800  $\mu\text{Eq}/\text{column}$  (4-mm  $\times$  25-cm).

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