

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Aug-2022
Document Type: USP Monographs
DocId: GUID-5F22A12C-CE90-461E-8B14-9F21F9B75503_2_en-US
DOI: https://doi.org/10.31003/USPNF_M67253_02_01
DOI Ref: jb3o3

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Potassium Bicarbonate and Potassium Chloride Effervescent Tablets for Oral Solution

DEFINITION

Potassium Bicarbonate and Potassium Chloride Effervescent Tablets for Oral Solution contain NLT 90.0% and NMT 110.0% of the labeled amounts of potassium (K) and chloride (Cl).

IDENTIFICATION

Change to read:

- **A.** ▲ (USP 1-Aug-2022)

Sample: 1 Tablet for Oral Solution

Analysis 1: Dissolve the *Sample* in 100 mL of [water](#), and collect the gas that evolves.

Acceptance criteria 1: The *Sample* effervesces when dissolved.

Analysis 2: Proceed as directed in [Identification Tests—General \(191\)](#), [Chemical Identification Tests, Bicarbonate](#) on the gas collected from *Analysis 1*.

Acceptance criteria 2: Meets the requirements of test A

- ▲ (USP 1-Aug-2022)

Add the following:

- ▲ **B.** The retention time of the potassium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 1: Potassium*. ▲ (USP 1-Aug-2022)

Add the following:

- ▲ **C.** The retention time of the chloride peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay, *Procedure 2: Chloride*. ▲ (USP 1-Aug-2022)

ASSAY

Change to read:

- **PROCEDURE 1: POTASSIUM**

▲ Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.

Mobile phase: 4 mM [nitric acid](#)

System suitability solution: 30 µg/mL of [USP Potassium Chloride RS](#) and 15 µg/mL of magnesium¹ in [water](#)

Standard solution: 30 µg/mL of [USP Potassium Chloride RS](#) in [water](#)

Sample stock solution: Nominally 10 mg/mL of potassium chloride prepared as follows. Finely powder NLT 20 Tablets for Oral Solution and transfer an appropriate portion of the powder to a suitable volumetric flask. Add about 10% of the final volume of [water](#), and swirl until effervescence ceases. Dilute with [water](#) to volume. [NOTE—Pass through a suitable filter if necessary.]

Sample solution: Nominally 30 µg/mL of potassium chloride in [water](#) from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: Direct conductivity

Columns

Guard: 4-mm × 0.5-cm; 5-µm packing [L76](#)

Analytical: 4-mm × 15-cm; 5-µm packing [L76](#)

Column temperature: 30°

Flow rate: 0.9 mL/min

Injection volume: 20 µL

Run time: NLT 2 times the retention time of potassium

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for the potassium and magnesium ions are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 3.0 between the potassium and magnesium ions, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of potassium (K) in the portion of Tablets for Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

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* (µg/mL)

C_U = nominal concentration of potassium chloride in the *Sample solution* (µg/mL)▲ (USP 1-Aug-2022)

Acceptance criteria: 90.0%–110.0%

Change to read:

• PROCEDURE 2: CHLORIDE

▲[NOTE—Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]

Standard solution, Sample stock solution, and Sample solution: Prepare as directed in Assay, *Procedure 1: Potassium*.

Mobile phase: 15 mM [sodium carbonate](#) and 1.5 mM [sodium hydroxide](#) in [water](#)

System suitability solution: 30 µg/mL of [USP Potassium Chloride RS](#) and 20 µg/mL of [USP Sodium Nitrite RS](#) in [water](#)

Chromatographic system

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

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4.0-mm × 0.5-cm; 4.6-µm packing [L91](#)

Analytical: 4.0-mm × 10-cm; 4.6-µm packing [L91](#)

Column temperature: 45°

Flow rate: 0.8 mL/min

Injection volume: 20 µL

Run time: NLT 3 times the retention time of chloride for *Standard solution* and *System suitability solution*; NLT 9 times the retention time of chloride for *Sample solution*

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for the chloride and nitrite ions are 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the chloride and nitrite ions, *System suitability solution*

Tailing factor: NMT 2.0 for the chloride ion, *Standard solution*

Relative standard deviation: NMT 2.0% for the chloride ion, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chloride (Cl) in the portion of Tablets for Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of chloride from the *Sample solution*