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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 magnesium[1] 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*

r_S = peak response of chloride 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%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight containers, ▲and store under cool and dry conditions not exceeding 30°.▲ (USP 1-Aug-2022)

Change to read:

• **Labeling:** The label states the potassium and chloride contents in terms of weight and in terms of milliequivalents. Where the ▲Tablets for Oral Solution▲ (USP 1-Aug-2022) are packaged in individual pouches, the label instructs the user not to open until the time of use.

Add the following:

▲• **USP Reference Standards ⟨11⟩**

USP Potassium Chloride RS

USP Sodium Nitrite RS▲ (USP 1-Aug-2022)

[1] From commercially available National Institute of Standards and Technology (NIST)-traceable standard solution for magnesium.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
POTASSIUM BICARBONATE AND POTASSIUM CHLORIDE EFFERVESCENT TABLETS FOR ORAL SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

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