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Potassium Bicarbonate Effervescent Tablets for Oral Solution

DEFINITION

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

IDENTIFICATION

Change to read:

- **A.** ▲The retention time of the potassium peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲

(USP 1-Aug-2021)

- **B.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Bicarbonate](#)

Sample solution: One Tablet dissolves in 100 mL of [water](#) with effervescence.

Acceptance criteria: The collected gas meets the requirements of test A.

ASSAY

Change to read:

- **PROCEDURE**

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

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

System suitability solution: 40 µg/mL of [USP Potassium Bicarbonate RS](#) and 15 µg/mL of magnesium¹ in [water](#)

Standard stock solution: 1000 µg/mL of potassium, equivalent to 2560 µg/mL of [USP Potassium Bicarbonate RS](#), prepared as follows.

Transfer an appropriate portion of [USP Potassium Bicarbonate RS](#) to a suitable volumetric flask. Add about 30% of the final volume of [water](#), swirl until effervescence ceases, and mix. Dilute with [water](#) to volume.

Standard solution: 15 µg/mL of potassium in [water](#) from the *Standard stock solution*

Sample stock solution: Nominally 5 mg/mL of potassium prepared as follows. Finely powder NLT 20 Tablets and transfer an appropriate portion of the powder to a suitable volumetric flask. Add about 30% of the final volume of [water](#), swirl until effervescence ceases, and mix. Dilute with [water](#) to volume. Pass through a suitable filter, if necessary.

Sample solution: Nominally 15 µg/mL of potassium in [water](#) from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: 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 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 potassium in the *Standard solution* ($\mu\text{g/mL}$)

C_U = nominal concentration of potassium in the *Sample solution* ($\mu\text{g/mL}$)

▲ (USP 1-Aug-2021)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

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

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from excessive heat.
- **LABELING:** The label states the potassium content in terms of weight and in terms of milliequivalents. Where the Tablets 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 Bicarbonate RS](#) ▲ (USP 1-Aug-2021)

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 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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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