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Potassium and Sodium Bicarbonates and Citric Acid Effervescent Tablets for Oral Solution

DEFINITION

Potassium and Sodium Bicarbonates and Citric Acid Effervescent Tablets for Oral Solution contain NLT 90.0% and NMT 110.0% of the labeled amounts of potassium bicarbonate ($KHCO_3$), sodium bicarbonate ($NaHCO_3$), and anhydrous citric acid ($C_6H_8O_7$).

IDENTIFICATION

Change to read:

• **A.** ▲▲ (Official 1-Feb-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*▲ (Official 1-Feb-2022)

Add the following:

▲• **B.** The retention times of the sodium and potassium peaks of the *Sample solutions* correspond to those of the *Standard solution*, as obtained in the *Assay, Procedure 1: Potassium Bicarbonate and Sodium Bicarbonate*.▲ (Official 1-Feb-2022)

Add the following:

▲• **C.** The retention time of the citrate peak of the *Sample solution* corresponds to that of *Standard solution 1*, as obtained in the *Assay, Procedure 2: Anhydrous Citric Acid*.▲ (Official 1-Feb-2022)

ASSAY

Change to read:

• ▲**Procedure 1:**▲ (Official 1-Feb-2022) **Potassium Bicarbonate and Sodium Bicarbonate**

▲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 each of USP Sodium Bicarbonate RS and USP Ammonium Chloride RS in water

Standard solution: 10 µg/mL of USP Potassium Bicarbonate RS and 30 µg/mL of USP Sodium Bicarbonate RS in water

Sample stock solution: Nominally 3 mg/mL of potassium bicarbonate prepared as follows. Finely powder Tablets for Oral Solution (NLT 20) and transfer an appropriate portion of the powder to a suitable volumetric flask. Add about 20% of the final volume of water, and swirl until effervescence ceases. Dilute with water to volume. [Note—Tablets for Oral Solution and powder are hygroscopic. After removal from the container, grind the Tablets for Oral Solution promptly in an atmosphere of low relative humidity, and weigh the powder promptly.]

Sample solution A: Nominally 10 µg/mL of potassium bicarbonate in water from the *Sample stock solution*

Sample solution B: Nominally 30 µg/mL of sodium bicarbonate 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 the potassium peak

System suitability

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

[NOTE—The relative retention times for the sodium, ammonium, and potassium peaks are 1.0, 1.2, and 1.7, respectively.]

Suitability requirements

Resolution: NLT 2.0 between the sodium and ammonium peaks, *System suitability solution*

Tailing factor: NMT 2.0 for the sodium and potassium peaks, *Standard solution*

Relative standard deviation: NMT 2.0% for the sodium and potassium peaks, *Standard solution*

Analysis

Samples: *Standard solution*, *Sample solution A*, and *Sample solution B*

Calculate the percentage of the labeled amount of potassium bicarbonate ($KHCO_3$) 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 *Sample solution A*

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

C_S = concentration of USP Potassium Bicarbonate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of potassium bicarbonate in *Sample solution A* (µg/mL)

Calculate the percentage of the labeled amount of sodium bicarbonate ($NaHCO_3$) 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 sodium from *Sample solution B*

r_S = peak response of sodium from the *Standard solution*

C_S = concentration of USP Sodium Bicarbonate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of sodium bicarbonate in *Sample solution B* (µg/mL)

▲ (Official 1-Feb-2022)

Acceptance criteria: 90.0%–110.0% ▲▲ (Official 1-Feb-2022)

Change to read:

• **▲PROCEDURE 2:▲ (OFFICIAL 1-FEB-2022) ANHYDROUS CITRIC ACID**

Mobile phase, Standard ▲solution▲ (Official 1-Feb-2022) 1, and **Chromatographic system:** Proceed as directed in *Assay for Citric Acid/Citrate and Phosphate ⟨345⟩*.

Sample solution: Nominally 20 µg/mL of citrate prepared as follows. Transfer the equivalent of 40 mg of anhydrous citric acid from the *Sample stock solution* ▲*(Official 1-Feb-2022)* in ▲*Assay, Procedure 1: Potassium Bicarbonate and Sodium Bicarbonate*▲ (Official 1-Feb-2022) into a suitable volumetric flask, and prepare as directed in *⟨345⟩, Assay, Procedure, Sample solution (for the assay of citric acid/citrate)*.

Analysis

Samples: *Standard ▲solution▲ (Official 1-Feb-2022) 1* and *Sample solution*

▲▲ (Official 1-Feb-2022)

Calculate the percentage of the labeled amount of anhydrous citric acid ($C_6H_8O_7$) in the portion of Tablets for Oral Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

r_S = peak response of citrate from *Standard ▲solution▲ (Official 1-Feb-2022) 1*

C_S = concentration of citrate in *Standard* ▲*solution*▲ *(Official 1-Feb-2022)* *1* (µg/mL)

C_U = nominal concentration of citrate in the *Sample solution* (µg/mL)

M_{r1} = molecular weight of anhydrous citric acid, 192.12

M_{r2} = molecular weight of citrate, 189.10

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **Acid-Neutralizing Capacity ⟨301⟩:** NLT 5 mEq of acid is consumed by the minimum single dose recommended in the labeling.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **Labeling:** Label Tablets for Oral Solution to state the sodium content. The label states also that the tablets are to be dissolved in water before being taken.

Add the following:

▲• **USP Reference Standards ⟨11⟩**

USP Ammonium Chloride RS

USP Potassium Bicarbonate RS

USP Sodium Bicarbonate RS▲ (Official 1-Feb-2022)

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

Topic/Question	Contact	Expert Committee
POTASSIUM AND SODIUM BICARBONATES AND CITRIC ACID 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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