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Potassium Citrate and Citric Acid Oral Solution

DEFINITION

Potassium Citrate and Citric Acid Oral Solution is a solution of Potassium Citrate and Citric Acid in a suitable aqueous medium. In each 100 mL, it contains NLT 7.55 g and NMT 8.35 g of potassium (K), and NLT 12.18 g and NMT 13.46 g of citrate ($C_6H_5O_7$), equivalent to NLT 20.9 g and NMT 23.1 g of potassium citrate monohydrate ($C_6H_5K_3O_7 \cdot H_2O$). It also contains NLT 6.34 g and NMT 7.02 g of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$).

[NOTE—The potassium ion content of Oral Solution is approximately 2 mEq/mL.]

IDENTIFICATION

Change to read:

• **A. ▲POTASSIUM:** 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)

• **B.**

Sample solution: Oral Solution and [hydrochloric acid](#) (50:50)

Analysis: To 2 mL of the *Sample solution* add 10 mL of [cobalt–uranyl acetate TS](#), and stir with a glass rod.

Acceptance criteria: No precipitate or turbidity forms after 15 min, and the *Sample solution* remains clear (absence of sodium).

Change to read:

• **C. ▲CITRATE:** 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: Citrate*. ▲ (USP 1-Aug-2022)

ASSAY

Change to read:

• **▲PROCEDURE 1: ▲ (USP 1-Aug-2022) POTASSIUM**

▲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 Citrate RS](#) and 15 µg/mL of magnesium¹ in [water](#)

Standard solution: 40 µg/mL of [USP Potassium Citrate RS](#) in [water](#)

Sample stock solution: Nominally 2 mg/mL of potassium citrate monohydrate prepared as follows. Transfer a suitable aliquot of Oral Solution to a suitable volumetric flask, and dilute with [water](#) to volume.

Sample solution: Nominally 40 µg/mL of potassium citrate monohydrate 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 potassium and magnesium ions are 1.0 and 1.3, respectively.]



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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 quantity, in g, of potassium (K) in each 100 mL of Oral Solution taken:

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

 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 Citrate RS](#) in the *Standard solution* (µg/mL) C_U = nominal concentration of potassium citrate monohydrate in the *Sample solution* (µg/mL) L = label claim of potassium for Oral Solution (g/100 mL)▲ (USP 1-Aug-2022)**Acceptance criteria:** 7.55–8.35 g of potassium (K) in each 100 mL**Change to read:**• ▲ **PROCEDURE 2:**▲ (USP 1-Aug-2022) **CITRATE****Mobile phase, Standard ▲solution**▲ (USP 1-Aug-2022) **1**, and **Chromatographic system:** Proceed as directed in the [Assay for Citric Acid/Citrate and Phosphate \(345\)](#).**Sample solution:** Transfer 15 mL of Oral Solution to a suitable volumetric flask, and proceed as directed in the *Sample solution (for the assay of citric acid/citrate)* in [\(345\)](#).**Analysis****Samples:** *Standard ▲solution*▲ (USP 1-Aug-2022) **1** and *Sample solution*

▲ (USP 1-Aug-2022)

Calculate the quantity, in g, of citrate ($C_6H_5O_7$) in each 100 mL of Oral Solution taken:

$$\text{Result} = \{[(r_U/r_S) \times (C_S/F) \times D] - A \times (M_{r1}/M_{r2})\} \times \Delta V \text{▲ (USP 1-Aug-2022)}$$

 r_U = peak response of citrate from the *Sample solution* r_S = peak response of citrate from *Standard ▲solution*▲ (USP 1-Aug-2022) **1** C_S = concentration of citrate in *Standard ▲solution*▲ (USP 1-Aug-2022) **1** (µg/mL) F = conversion factor, 10^6 µg/g D = dilution factor for the *Sample solution* A = ▲concentration▲ (USP 1-Aug-2022) of citric acid monohydrate in the Oral Solution determined in ▲*Assay, Procedure 3: Citric Acid*▲ (USP 1-Aug-2022) (g/mL) M_r = molecular weight of citrate, 189.10**1** M_r = molecular weight of citric acid monohydrate, 210.14**2**▲ V = volume of Oral Solution, 100 mL▲ (USP 1-Aug-2022)**Acceptance criteria:** 12.18–13.46 g of citrate ($C_6H_5O_7$), equivalent to 20.9–23.1 g of potassium citrate monohydrate ($C_6H_5K_3O_7 \cdot H_2O$) and 6.34–7.02 g of citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$), in each 100 mL**Change to read:**