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Potassium Phosphates Compounded Injection

DEFINITION

Potassium Phosphates Compounded Injection contains NLT 95.0% and NMT 105.0% of the labeled amount of monobasic potassium phosphate (KH_2PO_4) and dibasic potassium phosphate (K_2HPO_4). It contains no bacteriostat or other preservative.

Prepare Potassium Phosphates Compounded Injection containing 3 mM/mL of phosphorus and 4.4 mEq/mL of potassium as follows (see *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩*).

Monobasic Potassium Phosphate (anhydrous)	22.4 g
Dibasic Potassium Phosphate (anhydrous)	23.6 g
Sterile Water for Injection, a sufficient quantity to make	100 mL

Dissolve the *Dibasic Potassium Phosphate (anhydrous)* in 50 mL of *Sterile Water for Injection*. Dissolve the *Monobasic Potassium Phosphate (anhydrous)* in the solution and then bring to final volume with *Sterile Water for Injection*. [Note—May need to heat to 77° to fully dissolve. If heating is required, allow to reach room temperature prior to passing through a filter.] Pass through a filter of 1.2-µm pore size to remove particulate matter and sterilize by autoclave.

ASSAY

Change to read:

• **Procedure for Potassium**

Mobile phase: 8 mM methanesulfonic acid

Standard solution: 0.050 mg/mL of potassium prepared with USP Dibasic Potassium Phosphate RS and water

Sample solution: Transfer 74 µL of Injection to a 250-mL volumetric flask and dilute with water to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Conductivity

Column: ▲4-mm▲ (ERR 1-Sep-2024) × 25-cm; packing L97

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for potassium is about 5.1 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of potassium (K) in the portion of Injection 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* (mg/mL)

C_U = nominal concentration of potassium in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

Change to read:

• **Procedure for Phosphate**

Mobile phase: 40 mM sodium hydroxide

Standard solution: 0.230 mg/mL of phosphate prepared from USP Dibasic Potassium Phosphate RS in water

Sample solution: Transfer 0.2 mL of Injection to a 250-mL volumetric flask and dilute with water to volume.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Conductivity

Column: ▲4-mm▲ (ERR 1-Sep-2024) × 25-cm; packing L103

Column temperature: 30°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for phosphorus is about 5.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phosphate (PO_4) in the portion of Injection taken:

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

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

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

C_S = concentration of phosphate in the *Standard solution* (mg/mL)

C_U = nominal concentration of phosphate in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

• **pH ⟨791⟩:** 6.3–7.3

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 1.10 USP Endotoxin Units/mg of potassium phosphates

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in single-dose glass containers. Store at controlled room temperature.

• **Beyond-Use Date:** In the absence of performing and completing a sterility and endotoxin test, the storage conditions in *Pharmaceutical Compounding – Sterile Preparations ⟨797⟩, 14.3 Establishing a BUD for a CSP* apply. After successful completion of sterility and endotoxin testing, NMT 120 days after the date on which it was compounded when stored at controlled room temperature.

• **Labeling:** Label it to state the *Beyond-Use Date*. The label states the potassium content in terms of milliequivalents in a given volume, and states also the elemental phosphorus content in terms of millimoles in a given volume. Label it not for direct injection.

• **USP Reference Standards ⟨11⟩**

USP Dibasic Potassium Phosphate RS

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

Topic/Question	Contact	Expert Committee
POTASSIUM PHOSPHATES COMPOUNDED INJECTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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