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Sodium Phosphates Compounded Injection

Change to read:

DEFINITION

Sodium Phosphates Compounded Injection contains NLT 95.0% and NMT 105.0% of the labeled amount of ▲sodium and NLT 95.0% and NMT 105.0% of the labeled amount of phosphate.▲ (USP 1-May-2022) It contains no bacteriostat or other preservative.
Prepare Sodium Phosphates Compounded Injection containing 3 mM/mL of phosphorus and 4.0 mEq/mL of sodium as follows (see [Pharmaceutical Compounding—Sterile Preparations \(797\)](#)).

Monobasic Sodium Phosphate (anhydrous) ^a	24 g
Dibasic Sodium Phosphate (anhydrous)	14.2 g
Sterile Water for Injection, a sufficient quantity to make	100 mL

^a If anhydrous is not used, waters of hydration should be included in calculating the appropriate amount of sodium phosphates.

Dissolve the *Dibasic Sodium Phosphate (anhydrous)* in 50 mL of *Sterile Water for Injection*. Add and dissolve *Monobasic Sodium Phosphate (anhydrous)*, and 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 SODIUM

Mobile phase: 8 mM methanesulfonic acid

Standard solution: 0.025 mg/mL of sodium prepared with [USP Sodium Chloride RS](#) and water

Sample solution: Transfer ▲0.07▲ (USP 1-May-2022) mL of Injection to a ▲250-mL▲ (USP 1-May-2022) volumetric flask. ▲Add approximately 200 mL of water and vortex for 30 s.▲ (USP 1-May-2022) Dilute with water to volume ▲and transfer to a polypropylene ion chromatography vial.▲ (USP 1-May-2022)

Chromatographic system

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

Mode: LC

Detector: Conductivity

Column: ▲4-mm▲ (USP 1-May-2022) × 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 sodium is about 3.6 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 sodium (Na) in the portion of Injection taken:

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

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

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

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

C_U = nominal concentration of sodium 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 into a 250-mL volumetric flask. ▲Add approximately 200 mL of water and vortex for 30 s.▲ (USP

1-May-2022) Dilute with water to volume ▲and transfer to a polypropylene ion chromatography vial.▲ (USP 1-May-2022)

Chromatographic system

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

Mode: LC

Detector: Conductivity

Column: ▲4-mm▲ (USP 1-May-2022) × 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 (PO₄) 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 \(791\)](#): 5.3–6.3
- [STERILITY TESTS \(71\)](#): Meets the requirements
- [BACTERIAL ENDOTOXINS TEST \(85\)](#): NMT 1.10 USP Endotoxin Units/mg of sodium 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.

