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Sodium Nitrite Injection

DEFINITION

Sodium Nitrite Injection is a sterile solution of Sodium Nitrite in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of sodium nitrite (NaNO_2).

IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Sodium](#): Meets the requirements
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Nitrite](#): Meets the requirements

Change to read:

- **C.** The retention time of the ▲nitrite▲ (USP 1-Aug-2023) peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

▲[NOTE—Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]▲ (USP 1-Aug-2023)

Mobile phase: 2.7 mM sodium carbonate and 0.3 mM sodium bicarbonate in [water](#)

Standard solution: 0.12 mg/mL of [USP Sodium Nitrite RS](#)▲ and 1 µg/mL of [USP Sodium Nitrate RS](#)▲ (USP 1-Aug-2023) in [water](#)

Sample solution: Nominally 0.12 mg/mL of sodium nitrite in [water](#) from a suitable volume of Injection

Chromatographic system

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

Mode: Ion chromatography

Detector: Conductivity with suppression

Columns

Guard: 4-mm × 50-mm; ▲13-µm▲ (USP 1-Aug-2023) packing ▲[L110](#)▲ (USP 1-Aug-2023)

Analytical: 4-mm × 200-mm; 9-µm packing [L105](#)

Flow rate: 1.5 mL/min

Injection volume: 25 µL

Run time: NLT 4 times the retention time of nitrite

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for ▲nitrite and nitrate▲ (USP 1-Aug-2023) ions are 1.0 and 1.85, respectively.]

Suitability requirements

Tailing factor: NMT 2.0 ▲for nitrite▲ (USP 1-Aug-2023)

Relative standard deviation: NMT 2.0% ▲for nitrite▲ (USP 1-Aug-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of sodium nitrite (NaNO_2) in the portion of Injection taken:

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

r_U = peak response ▲of nitrite▲ (USP 1-Aug-2023) from the *Sample solution*

r_s = peak response of nitrite (USP 1-Aug-2023) from the *Standard solution*

C_s = concentration of [USP Sodium Nitrite RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of sodium nitrite in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

IMPURITIES

Change to read:

• LIMIT OF SODIUM NITRATE

▲[NOTE—Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]▲ (USP 1-Aug-2023)

Mobile phase, ▲Standard solution,▲ (USP 1-Aug-2023) Sample solution, and Chromatographic system: Proceed as directed in the Assay.

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for nitrite and nitrate are 1.0 and about 1.85, respectively.]

Suitability requirements

Tailing factor: NMT 2.0 ▲for nitrite▲ (USP 1-Aug-2023)

Relative standard deviation: NMT 2.0% ▲for nitrite and NMT 5% for nitrate▲ (USP 1-Aug-2023)

Analysis

Samples: *Sample solution*

Calculate the percentage of sodium nitrate (NaNO_3) in the portion of Injection taken:

$$\text{Result} = (r_u/r_s) \times (1/F) \times 100$$

r_u = peak response of nitrate from the *Sample solution*

r_s = peak response of nitrite from the *Sample solution*

F = relative response factor of sodium nitrate, 0.7

Acceptance criteria: NMT 0.5%

Change to read:

• LIMIT OF NITROGEN OXIDE (NO_x) RELATED IMPURITIES

▲[NOTE—Use water with a resistivity of NLT 18 megohm-cm to prepare the solutions.]▲ (USP 1-Aug-2023)

Blank solution 1: 0.1 N potassium chloride prepared as follows. Dissolve 7.46 g of [potassium chloride](#) in 1 L of [water](#).

Blank solution 2: Acidified 0.1 N potassium chloride prepared as follows. In a 500-mL volumetric flask pipet 15-mL of 1 N hydrochloric acid and dilute with 0.1 N potassium chloride to volume.

Standard solution: 4.920 mg/mL of ▲[USP Sodium Nitrite RS](#)▲ (USP 1-Aug-2023) in [water](#) equivalent to 1000 µg/mL of ▲nitrogen oxide (NO_x)▲ (USP 1-Aug-2023)

Sample solution: Dilute 10.0 mL of Injection with [water](#) to 50.0 mL. Store between 2° and 8°. Use 40 mL for each measurement.

System suitability

[NOTE—Under acidic conditions of pH less than 1.8, the nitrite is converted to equivalent amounts of nitrogen oxides with different oxidation states.]

Samples: *Blank solution 2* and *Standard solution*

Suitability requirements: Generate a calibration curve of the mV readings for *Blank solution 2*, and a sequential addition of 100 µL, 100 µL, 800 µL, and 9 mL of the *Standard solution* to *Blank solution 2* versus the log of the concentrations of the nitrogen oxide (NO_x) in the solution. Use a pH meter equipped with a suitable nitrogen oxide (NO_x) electrode to obtain the mV readings. Perform a linear regression without the zero concentration point and determine the slope and correlation coefficient (R). The slope must be between 54 and 60 mV and the linear regression coefficient is NLT 0.995.

Analysis

Samples: *Blank solution 1*, *Blank solution 2*, *Standard solution*, and *Sample solution*

Analyze the samples in the following order and obtain the pH meter readings in mV for 40-mL portions each of *Blank solution 1* in duplicate, *Sample solution* in duplicate, and *Blank solution 1*; and 100-mL portions each of *Blank solution 2*, and *Blank solution 2* plus 100 µL of *Standard solution*. [NOTE—This solution contains 1 µg/mL of nitrogen oxide (NO_x).] Repeat the measurements.