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Sodium Nitrite

Change to read:

$NaNO_2$ ▲68.99▲ (USP 1-Aug-2023)

Nitrous acid, sodium salt;

Sodium nitrite CAS RN®: 7632-00-0; UNII: M0KG633D4F.

DEFINITION

Sodium Nitrite contains NLT 98.0% and NMT 102.0% of sodium nitrite ($NaNO_2$), calculated on the dried basis.

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: 0.12 mg/mL of Sodium Nitrite in water

Chromatographic system

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

Mode: LC

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 1.5% ▲for nitrite▲ (USP 1-Aug-2023)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium nitrite ($NaNO_2$) in the portion of Sodium Nitrite 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 = concentration of Sodium Nitrite in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

Change to read:

• **Limit of Aluminum, Iron, and Selenium**

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

Internal standard stock solution: To 2 mL each of commercially available 1 mg/mL scandium (for aluminum) and yttrium (for iron) and 10 mg/mL germanium (for selenium) standards in a 100-mL volumetric flask, add 2 mL of nitric acid and dilute with water to volume.

Internal standard solution: To 0.5 mL of the *Internal standard stock solution* in a 10-mL volumetric flask, add 0.5 mL of nitric acid and dilute with water to volume.

Blank solution: Dilute with water to volume, 0.125 mL of the *Internal standard solution*, 0.5 mL of nitric acid, and 0.5 mL of 80 ppm gold solution in a 50-mL volumetric flask.

Standard solutions: 2, 5, 50, and 100 ppb solutions for aluminum and selenium; 0, 50, 100, 500, and 1000 ppb for iron as follows. To suitable amounts of commercially available aluminum, selenium, and iron standard solutions in a 50-mL volumetric flask, add 0.125 mL of the *Internal standard solution*, 0.5 mL of nitric acid, and 0.5 mL of 80 ppm gold solution, and dilute with water to volume.

Sample solution: To 1 g of Sodium Nitrite in a 50-mL volumetric flask, add 0.125 mL of the *Internal standard solution*, 2.5 mL of nitric acid, and 0.5 mL of 80 ppm gold solution, and dilute with water to volume.

Instrumental conditions

(See *Plasma Spectrochemistry ⟨730⟩*.)

Mode: Inductively coupled plasma–mass spectrometer (ICP–MS)

Spectrometer: Quadrupole mass spectrometer

Detector: Ion detector

System suitability

Sample: *Standard solutions*

Suitability requirements: Before analyzing samples, the instrument must pass a suitable performance check. Generate the calibration curve using the corresponding *Standard solutions* for each element under test. The linear regression coefficient is NLT 0.999.

Analysis

Sample: *Sample solution*

Determine the concentration of each element in the *Sample solution* using the calibration curve.

▲Calculate the amount of each element in the portion of Sodium Nitrite taken:

$$\text{Result} = [(C_t \times V)/W]$$

C_t = concentration of each element in the *Sample solution* determined from the calibration curve (µg/mL or ppm)

V = volume of the *Sample solution*, 50 mL

W = weight of Sodium Nitrite taken (g)

▲ (USP 1-Aug-2023)

Acceptance criteria: See *Table 1*.

Table 1

Element	Isotope (amu)	Acceptance Criteria, NMT (ppm)
Aluminum	27	2
Iron	57	10
Selenium	82	30

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 ▲▲ (USP 1-Aug-2023)

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 1.5% ▲for nitrite and NMT 5% for nitrate▲ (USP 1-Aug-2023)

Analysis

Sample: *Sample solution*

Calculate the percentage of sodium nitrate ($NaNO_3$) in the portion of ▲Sodium Nitrite▲ (USP 1-Aug-2023) 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 for nitrate, 0.7

Acceptance criteria: NMT 0.4%

Change to read:

• **LIMIT OF CALCIUM AND POTASSIUM**

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

Internal standard solution: 40 ppm scandium solution prepared from a suitable commercially available 1000 ppm high purity scandium standard solution in water

Blank solution: To 0.5 mL of the *Internal standard solution* in a 50-mL volumetric flask, add 0.5 mL of nitric acid and dilute with water to volume.

Standard solutions: 2.5, 5.0, 7.5, and 10.0 ppm of calcium and potassium prepared as follows. To suitable amounts of the respective commercially available calcium and potassium standard solutions in a suitable volumetric flask, add 0.5 mL of the *Internal standard solution* and 0.5 mL of nitric acid, and dilute with water to 50 mL.

Sample solution: To 1 g of Sodium Nitrite in a 50-mL volumetric flask, add 0.5 mL of the *Internal standard solution* and 2.5 mL of nitric acid, and dilute with water to volume.

Instrumental conditions

(See *Plasma Spectrochemistry ⟨730⟩*.)

Mode: Inductively coupled plasma–mass spectrometer (ICP–MS)

Spectrometer: Quadrupole mass spectrometer

Detector: Ion detector

System suitability

Sample: *Standard solutions*

Suitability requirements: Before analyzing samples, the instrument must pass a suitable performance check. Generate the calibration curve using the *Standard solutions* of the corresponding elements. The linear regression coefficient is NLT 0.999.

Analysis

Sample: *Sample solution*

Determine the concentration of each element in the *Sample solution* using the calibration curve.

▲Calculate the amount of each element in the portion of Sodium Nitrite taken:

$$\text{Result} = [(C_t \times V)/W]$$

C_t = concentration of each element in the *Sample solution* determined from the calibration curve (ppm or µg/mL)

V = volume of the *Sample solution*, 50 mL

W = weight of Sodium Nitrite taken (g)

▲ (USP 1-Aug-2023)

Acceptance criteria: See *Table 2*.

Table 2

Element	Isotope (amu)	Acceptance Criteria, NMT (ppm)
Calcium	44	100

Element	Isotope (amu)	Acceptance Criteria, NMT (ppm)
Potassium	39	50

Change to read:

• **Limit of Carbonate**

All carbonate solutions must be prepared fresh and stored in tightly sealed vials and stored in a cool area away from excessive heat.

Standard stock solution: 1 mg/mL of carbonate prepared as follows. Dissolve 0.177 g of ▲USP Sodium Carbonate Anhydrous RS▲ (USP 1-Aug-2023) in a 100-mL volumetric flask, and dilute with water to volume.

Standard solutions: 0.50, 1.0, 2.0, 4.0, and 5.0 µg/mL carbonate in water from the *Standard stock solution*

Sample solution: Transfer 1.0 g of Sodium Nitrite into a 100-mL volumetric flask, and dilute with water to volume.

▲Instrumental conditions

(See *Total Organic Carbon ⟨643⟩*.)▲ (USP 1-Aug-2023)

System suitability: Before analyzing samples, the total organic carbon (TOC) analyzer must pass a suitable performance check. Generate the calibration curve using the *Standard solutions*. The linear regression coefficient is NLT 0.995; the relative standard deviation for each *Standard solution* is NMT 10%.

Analysis

Sample: *Sample solution*

Calculate the percentage of carbonate in the portion of ▲Sodium Nitrite▲ (USP 1-Aug-2023) taken:

$$\text{Result} = [(C_t \times {}^{\blacktriangle}V_{\blacktriangle\ (\text{USP 1-Aug-2023})})/W] \times 100$$

C_t = concentration of carbonate ▲in the *Sample solution* determined from the calibration curve▲ (USP 1-Aug-2023) (g/mL)

$^{\blacktriangle}V$ = volume of the *Sample solution*, 100 mL▲ (USP 1-Aug-2023)

W = weight of ▲Sodium Nitrite▲ (USP 1-Aug-2023) taken (g)

Acceptance criteria: NMT 0.02%

Change to read:

• **Total Non-Purgeable Organic Content**

Standard stock solution: Equivalent to 250 µg/mL of total organic carbon prepared as follows. Weigh 9 mg of USP Sucrose RS in a suitable flask, and add 15 mL of water.

Standard solutions: ▲Equivalent to▲ (USP 1-Aug-2023) 0.5, 2.0, and 10 µg/mL of total organic carbon in water from the *Standard stock solution*

Sample solution: Dissolve and dilute with water to volume, 5.0 g of Sodium Nitrite in a 100-mL volumetric flask.

▲Instrumental conditions

(See *Total Organic Carbon ⟨643⟩*.)▲ (USP 1-Aug-2023)

System suitability: Before analyzing samples, the total organic carbon analyzer instrument must pass a suitable performance check. Generate the calibration curve using the *Standard solutions*. The linear regression coefficient is NLT 0.99; relative standard deviation for the 2 µg/mLand 10 µg/mL calibration standards is NMT 15%.

Analysis

Sample: *Sample solution*

Calculate the amount, in ppm, of non-purgeable organic content present in the ▲Sodium Nitrite▲ (USP 1-Aug-2023) taken:

$$\text{Result} = [(C_t \times {}^{\blacktriangle}V_{\blacktriangle\ (\text{USP 1-Aug-2023})})/W]$$

C_t = amount of non-purgeable organic content as determined ▲from the calibration curve (µg/mL)

V = volume of the *Sample solution*, 100 mL▲ (USP 1-Aug-2023)

W = weight of ▲Sodium Nitrite▲ (USP 1-Aug-2023) taken (g)

Acceptance criteria: NMT 10 ppm

Change to read:

• **Limit of Sulfate**

Standard solution: 0.0148 mg/mL of ▲USP Sodium Sulfate Anhydrous RS▲ (USP 1-Aug-2023) in water

Sample solution: 100 mg/mL of Sodium Nitrite in water

Analysis

Samples: ▲*Standard solution* and▲ (USP 1-Aug-2023) *Sample solution*

Evaporate 5 mL of the ▲*Standard solution* or▲ (USP 1-Aug-2023) *Sample solution* to dryness. Add 1 mL of dilute hydrochloric acid (prepared by adding 1 mL of hydrochloric acid to 19 mL of water). Pass through a prewashed small filter paper, and wash with two 2-mL portions of water. Dilute to 10 mL, and add 1 mL of barium chloride TS. Compare turbidity in the *Standard solution* and *Sample solution*, 10 min after adding the barium chloride TS.

Acceptance criteria: Any turbidity in the *Sample solution* should not exceed the turbidity in the *Standard solution* (NMT 0.01%).

Change to read:

• **Limit of Chloride**

Standard solution: 0.0165 mg/mL of ▲USP Sodium Chloride RS▲ (USP 1-Aug-2023) in water

Sample solution: 100 mg/mL of Sodium Nitrite in water

Analysis

Samples: *Standard solution* and *Sample solution*

To 2.0 mL of the *Sample solution* in a suitable test tube add 10 mL of water and 1 mL of glacial acetic acid and boil for 5 min. Pass through a chlorine-free filter paper, and dilute with water to 20 mL. Dilute 1 mL of the *Standard solution* with water to 20 mL in a separate test tube. Add 1 mL of nitric acid and 1 mL of 0.1 N silver nitrate. Allow to stand for 5 min protected from light and compare using a black background.

Acceptance criteria: Any turbidity in the *Sample solution* should not exceed the turbidity in the *Standard solution* (NMT 50 ppm).

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test** ⟨85⟩**:** ▲Meets the requirements▲ (USP 1-Aug-2023)

• **Microbial Enumeration Tests** ⟨61⟩**:** NMT 100 cfu/g, total aerobic microbial count and NMT 20 cfu/g, total yeasts and molds

Change to read:

• **pH** ⟨791⟩

▲**Sample solution:** 10% of Sodium Nitrite in water at 25°▲ (USP 1-Aug-2023)

Acceptance criteria: 7.0–9.0

Change to read:

• **Insoluble Matter**

Sample solution: ▲Dissolve 20 g▲ (USP 1-Aug-2023) of Sodium Nitrite ▲in 200 mL of▲ (USP 1-Aug-2023) water.

Analysis: Heat the *Sample solution* to boiling in a covered beaker at about 100° for 1 h. Pass the hot solution through a suitable crucible filter of 10–15 µm pore size. Wash the beaker and filter with hot water, dry at 105°, cool in a desiccator, and weigh the residue.

Acceptance criteria: ▲NMT 1 mg (0.005%)▲ (USP 1-Aug-2023)

• **Loss on Drying** ⟨731⟩

Analysis: Dry over silica gel for 4 h.

Acceptance criteria: NMT 0.25%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers and store at 25°, excursions permitted between 15° and 30°.

Change to read:

• **USP Reference Standards** ⟨11⟩

▲ USP Sodium Carbonate Anhydrous RS
USP Sodium Chloride RS
USP Sodium Nitrate RS▲ (USP 1-Aug-2023)
USP Sodium Nitrite RS

▲ USP Sodium Sulfate Anhydrous RS▲ (USP 1-Aug-2023)
USP Sucrose RS

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

Topic/Question	Contact	Expert Committee
SODIUM NITRITE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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