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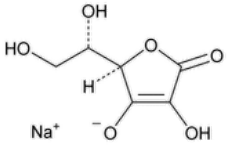
Sodium Ascorbate



$C_6H_7NaO_6$ 198.11

L-Ascorbic acid, monosodium salt;

Monosodium L-ascorbate CAS RN®: 134-03-2.

DEFINITION

Sodium Ascorbate contains NLT 99.0% and NMT 101.0% of sodium ascorbate ($C_6H_7NaO_6$), calculated on the dried basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197M

Sample: Use undried Sodium Ascorbate.

Acceptance criteria: Meets the requirements

Change to read:

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

Change to read:

• **C.** ▲Characteristic emission lines for sodium at 330.2, 589.0, and 589.6 nm of the *Sample solution* correspond to those of the *Standard solution*, as obtained in the *Content of Sodium*.▲ (USP 1-Aug-2023)

ASSAY

Change to read:

• **Procedure**

▲**Mobile phase:** 50 mM monobasic sodium phosphate. Adjust with phosphoric acid to a pH of 2.5.

Diluent: Dissolve 73 g of metaphosphoric acid in 1.0 L of water.

Standard stock solution: 2 mg/mL of USP Ascorbic Acid RS in *Diluent*

Standard solution: 0.2 mg/mL of USP Ascorbic Acid RS in *Mobile phase*, from the *Standard stock solution*

Sample stock solution: Transfer 220 mg of Sodium Ascorbate to a 100-mL volumetric flask. Dissolve and dilute with *Diluent* to volume.

Sample solution: 0.22 mg/mL of Sodium Ascorbate in *Mobile phase*, from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm × 25-cm; 5-µm packing L96

Temperature

Autosampler: 5°

Column: 10°

Flow rate: 0.8 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0% for the ascorbate peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of sodium ascorbate ($C_6H_7NaO_6$) in the portion of sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of ascorbic acid from the *Sample solution*

r_S = peak response of ascorbic acid from the *Standard solution*

C_S = concentration of USP Ascorbic Acid RS in the *Standard solution* (mg/mL)

C_U = concentration of Sodium Ascorbate in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of sodium ascorbate, 198.11

M_{r2} = molecular weight of ascorbic acid, 176.12

Acceptance criteria: 99.0%–101.0% on the dried basis ▲(USP 1-Aug-2023)

Add the following:

▲OTHER COMPONENTS

• **Content of Sodium**

Stock aqua regia solution: Trace metal grade hydrochloric acid and trace metal grade nitric acid (3:1) prepared as follows. Add nitric acid to hydrochloric acid and mix. [Note—Periodically vent the solution in an appropriate fume hood.]

Diluent: *Stock aqua regia solution* and deionized water (1:9) prepared as follows. Add 1 volume of *Stock aqua regia solution* to 2 volumes of deionized water. Dilute with additional deionized water to volume, and mix well.

Standard stock solution: Using a commercially available sodium standard solution in 5% (v/v) nitric acid solution, pipet an appropriate amount of sodium standard solution into a volumetric flask and dilute with 5% (v/v) nitric acid solution to obtain a 1000-mg/L sodium solution.

Standard solution A: Dilute the *Standard stock solution* with *Diluent* to obtain a concentration of 24.0 mg/L.

Standard solution B: Dilute the *Standard stock solution* with *Diluent* to obtain a concentration of 26.0 mg/L.

Standard solution C: Dilute the *Standard stock solution* with *Diluent* to obtain a concentration of 48.0 mg/L.

Standard solution D: Dilute the *Standard stock solution* with *Diluent* to obtain a concentration of 60.0 mg/L.

Standard solution E: Dilute the *Standard stock solution* with *Diluent* to obtain a concentration of 72.0 mg/L.

Standard solution F: Dilute the *Standard stock solution* with *Diluent* to obtain a concentration of 84.0 mg/L.

Sample solution: Transfer 26 mg of Sodium Ascorbate, accurately weighed and equivalent to about 3 mg of sodium, to a 50-mL volumetric flask. Add about 40 mL of *Diluent*, sonicate to dissolve, and dilute with *Diluent* to volume.

Blank: *Diluent*

Instrumental conditions

(See *Plasma Spectrochemistry* ⟨730⟩.)

Mode: ICP–OES

Emission wavelength: About 589.6 nm or optimized wavelength for sodium. For *Identification C*, detect additional sodium emission lines at 330.2 and 589.0 nm. [Note—The operating conditions may be developed and optimized based on the manufacturer's recommendation. The wavelengths selected should be demonstrated experimentally to provide sufficient specificity, sensitivity, linearity, accuracy, and precision.]

System suitability

Sample: *Standard solutions*

Suitability requirements

Correlation coefficient: NLT 0.99, determined from the linear calibration constructed in the *Analysis*, *Standard solutions A–F*

Relative standard deviation: NMT 2.0% from five replicate analyses, *Standard solution D*

Analysis

Samples: *Diluent*, *Standard solutions*, and *Sample solution*

Construct a linear calibration curve using the intensity of the emission from the six *Standard solutions*. Determine the emission lines of sodium in each *Standard solution* and the *Sample solution*. Plot the emission values of sodium in the *Standard solutions* versus the

concentration, in mg/L, of sodium, and draw the straight line best fitting the plotted points. From the graph, determine the concentration (*C*), in mg/L, of sodium in the *Sample solution*.

Calculate the percentage of sodium in the portion of Sodium Ascorbate taken:

$$\text{Result} = C \times (V/W) \times 100$$

C = concentration of sodium in the *Sample solution* (mg/L)

V = volume of the *Sample solution* (L)

W = sample weight (mg)

Acceptance criteria: 11.1%–12.1% on the dried basis▲ (USP 1-Aug-2023)

SPECIFIC TESTS

• **Optical Rotation** ⟨781S⟩, *Procedures, Specific Rotation*

Sample solution: 100 mg/mL in carbon dioxide-free water. Use the solution immediately after preparation.

Acceptance criteria: +103° to +108°

• **pH** ⟨791⟩

Sample solution: 100-mg/mL solution

Acceptance criteria: 7.0–8.0

• **Loss on Drying** ⟨731⟩

Analysis: Dry under vacuum over phosphorous pentoxide at 60° for 4 h.

Acceptance criteria: NMT 0.25%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

Change to read:

• **USP Reference Standards** ⟨11⟩

▲USP Ascorbic Acid RS▲ (USP 1-Aug-2023)

USP Sodium Ascorbate RS

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

Topic/Question	Contact	Expert Committee
SODIUM ASCORBATE	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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