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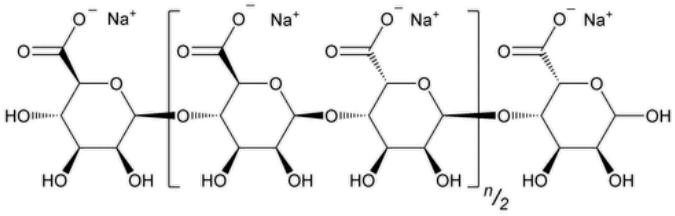
Sodium Alginate



$(C_6H_7NaO_6)_{n+2}$
Alginic acid, sodium salt;
Sodium alginate

CAS RN®: 9005-38-3.

DEFINITION

Sodium Alginate is the purified carbohydrate product extracted from brown seaweeds by the use of dilute alkali. It consists chiefly of the sodium salt of Alginic Acid, a linear, unbranched, amorphous copolymer of β-D-mannuronic acid (M) and α-L-guluronic acid (G) linked to each other by 1→4 glycosidic bonds. The M and G units in the alginates may be randomly or non-randomly arrayed as heterogeneous or homogeneous sequences. It contains NLT 90.8% and NMT 106.0% of sodium alginate, calculated on the dried basis. The typical average molecular weight for Sodium Alginate is in the range of 10,000–600,000 g/mol.

IDENTIFICATION

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

• **B.**

Sample solution 1: A solution (1 in 100)
Analysis 1: To 5 mL of *Sample solution 1* add 1 mL of calcium chloride TS.
Acceptance criteria 1: A voluminous, gelatinous precipitate is formed immediately.
Sample solution 2: A solution (1 in 100)
Analysis 2: To 10 mL of *Sample solution 2* add 1 mL of 4 N sulfuric acid.
Acceptance criteria 2: A heavy, gelatinous precipitate is formed.

• **C. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium***

Sample solution: Ignite 0.2 g of Sodium Alginate at 700° for 2 h, and dissolve the residue in 2 mL of water.
15% Potassium carbonate solution: Dissolve 7.5 g of potassium carbonate in 50 mL of water and mix well.
Analysis 1: Transfer 2 mL of the *Sample solution* to a test tube, add 2 mL of *15% Potassium carbonate solution*, and heat to boiling.
Acceptance criteria 1: No precipitate is formed.
Analysis 2: To the test tube from *Analysis 1* add 4 mL of potassium pyroantimonate TS, heat to boiling, cool in ice water, and rub the inside of the test tube with a glass rod.
Acceptance criteria 2: A dense precipitate is formed.

ASSAY

Change to read:

• **Procedure**

Transfer 200 mL of 0.5 N hydrochloric acid VS to a 400-mL beaker. Place it on a magnetic stirrer and stir. Weigh about 1.0 g of Sodium Alginate. Add the sample to acid with stirring. Stir for 30 min and leave the solution for another 30 min. Filter through a suitable glass crucible. Wash the filter with water until the pH of the filtrate water is neutral. Transfer the contents of the filter crucible to a beaker. Flush the

filter crucible with water. Place the beaker on a stirrer and start stirring. Add a few drops of phenolphthalein indicator solution and titrate with 0.5 N sodium hydroxide until it is a stable pink color. Note the amount of sodium hydroxide consumed in milliliters (V_2).

Analysis: Each milliliter of 0.5 N sodium hydroxide consumed is equivalent to 55.50 mg of Sodium Alginate (equivalent weight 222.00g/mol). Calculate the percentage of sodium alginate in the portion of Sodium Alginate taken:

$$\text{Result} = (V_2 \times N \times W_E \blacktriangle \times 10 \blacktriangle_{\text{(ERR 1-Sep-2023)}})/(W \times D)$$

V_2 = volume of sodium hydroxide consumed (mL)

N = normality of sodium hydroxide solution

W_E = equivalent weight of Sodium Alginate, 222.0 g/mol

W = sample weight (g)

D = percent dry matter value for the sample

Acceptance criteria: 90.8%–106.0% on the dried basis

IMPURITIES

• **Limit of Lead and Arsenic**

[Note—When water is specified as the diluent, use deionized ultra-filtered water. Use of glass volumetric flasks is discouraged.]

Diluent: Weigh around 3.5 g of sodium nitrate in a 1000-mL volumetric flask. Add 500 mL of water to dissolve. Add 170 mL of nitric acid, ultratrace, and mix. Cool to room temperature and dilute with water to volume.

Standard stock solution: Into a 10-mL volumetric flask, transfer 100 µL of a standard solution containing 1000 mg/L of arsenic[1] and 500 µL of a standard solution containing 1000 mg/L of lead.[2] Add 1–2 drops of nitric acid, ultratrace. Dilute with water to volume.

Internal standard solution: Transfer 1.0 mL of a standard solution containing 10,000 mg/L of yttrium[3] to a 100-mL volumetric flask. Add 1–2 drops of nitric acid, ultratrace, and dilute with water to volume. [Note—The concentration of the *Internal standard solution* can be adjusted if a high number of signal counts from the *Internal standard solution* causes an artifact.]

Calibration standard solution A: Into a separate 100-mL volumetric flask, prepare a solution containing 0.01 µg/mL of arsenic and 0.05 µg/mL of lead from the *Standard stock solution*. To each flask, add 100 µL of the *Internal standard solution* and 20 µL of a standard solution containing 1000 mg/L of gold.[4] Dilute with *Diluent* to volume.

Calibration standard solution B: Into a separate 100-mL volumetric flask, prepare a solution containing 0.02 µg/mL of arsenic and 0.1 µg/mL of lead from the *Standard stock solution*. To each flask, add 100 µL of the *Internal standard solution* and 20 µL of a standard solution containing 1000 mg/L of gold. Dilute with *Diluent* to volume.

Calibration standard solution C: Into a separate 100-mL volumetric flask, prepare a solution containing 0.04 µg/mL of arsenic and 0.2 µg/mL of lead from the *Standard stock solution*. To each flask, add 100 µL of the *Internal standard solution* and 20 µL of a standard solution containing 1000 mg/L of gold. Dilute with *Diluent* to volume.

Blank solution: In a 100-mL volumetric flask, add 100 µL of the *Internal standard solution*. Add 20 µL of a standard solution containing 1000 mg/L of gold to the same flask. Dilute with *Diluent* to volume, and mix well.

Sample solution: Weigh about 0.50 g of Sodium Alginate in a Teflon pressure vessel. Add 10 mL of nitric acid, ultratrace. Add 10 µL of a standard solution containing 1000 mg/L of gold. Screw the cap of the pressure vessel and commence digestion in a microwave digester per the program given in *Table 1*.

Table 1

Sequence	Temperature (°)	Power (W)	Time (min)
Ramp to	80	400	5
Hold at	80	400	5
Ramp to	150	800	10
Hold at	150	800	10
Ramp to	170	800	10

Sequence	Temperature (°)	Power (W)	Time (min)
Hold at	170	800	10
Cool	—	0	—

Once completed, allow it to cool. Rinse the vessel using water and transfer the rinsate to a separate 50-mL volumetric flask. Add 50 µL of the *Internal standard solution*. Dilute with water to volume, and mix well.

Instrumental conditions

(See *Plasma Spectrochemistry* ⟨730⟩.)

Mode: ICP–OES

Emission wavelengths: 189.042 nm for arsenic, 220.353 nm for lead, and 224.306 nm for yttrium. Set the sample read time and other instrument parameters as appropriate or as recommended by the instrument manufacturer.

System suitability

Samples: *Calibration standard solutions A–C*, *Blank solution*, and *Sample solution*

Suitability requirements

[NOTE—Instrument performance must be verified to conform to the manufacturer's specifications for resolution and sensitivity. Before analyzing samples, the instrument must pass a suitable performance check. Additional system suitability parameters can be used as per the instrument manufacturer's recommendations, along with the internal quality requirements.]

Correlation coefficient: NLT 0.999, determined from the *Calibration curve* constructed in the *Analysis*

Analysis

Samples: *Calibration standard solutions A–C*, *Blank solution*, and *Sample solution*. [NOTE—The following analysis is described for one type of ICP–OES instrument. If a different ICP–OES instrument is used, follow the instrument manufacturer's recommendations for operation.] Take 3 replicate scans with the integration set as recommended by the instrument manufacturer. Follow the instrument manufacturer's recommendations for delivering the sample. Flush the samples through the system before analysis. Program a read delay into the sampling routine to allow for fluid flow equilibration after the high-speed flush, before the first analytical read of the sample. Between samples, wash the pumping system by flushing the *Blank solution*. Analyze the *Sample solution* on the ICP.

Calibration curve: Generate the calibration curve using the *Blank solution* and *Calibration standard solutions A–C* as follows. Scan the *Internal standard solution* while running the *Blank solution* to measure the intensity of the yttrium emission. Hold this value constant throughout the remainder of the test. Separately scan the *Blank solution*, *Calibration standard solutions A–C*, and *Internal standard solution*. Normalize the yttrium intensity to the value of the *Internal standard solution*. Apply this normalization factor to the intensity of the respective elements, which is then referred to as the corrected intensity. Obtain the concentration of arsenic and lead (*C*), in µg/mL, in the *Sample solution*, through the calibration curve. Plot the corrected intensity versus the known concentrations, in µg/mL, of arsenic and lead.

Calculate the content in µg/g (ppm) of arsenic and lead in the portion of Sodium Alginate taken:

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

C = concentration of arsenic/lead in the *Sample solution* obtained from the *Calibration curve* (µg/mL)

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

W = weight of Sodium Alginate taken to prepare the *Sample solution* (g)

Acceptance criteria: NMT 1.5 µg/g of arsenic and 10 µg/g of lead

SPECIFIC TESTS

• **MICROBIAL ENUMERATION TESTS** ⟨61⟩ and **TESTS FOR SPECIFIED MICROORGANISMS** ⟨62⟩**:** The total bacterial count does not exceed 200 cfu/g. The tests for *Salmonella* species and *Escherichia coli* are negative.

• **LOSS ON DRYING** ⟨731⟩

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 15.0%

• **ARTICLES OF BOTANICAL ORIGIN** ⟨561⟩, *Methods of Analysis, Total Ash*

Analysis: Proceed as directed in the chapter, carefully igniting 3 g in a tared platinum dish until the residue is thoroughly carbonized (5 min), and then igniting in a muffle furnace at a temperature of 800 ± 25° until the carbon is completely burned off (approximately 75 min).

Acceptance criteria: 18.0%–27.0% of ash on the dried basis

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Sodium Alginate RS

[1] Arsenic ICP standard solutions are commercially available. A suitable ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).

[2] Lead ICP standard solutions are commercially available. A suitable ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).

[3] Yttrium ICP standard solutions are commercially available. A suitable ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).

[4] Gold standard solutions are commercially available. A suitable ICP standard is available from LGC (www.lgcstandards.com) or Millipore Sigma (www.sigmaaldrich.com).

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

Topic/Question	Contact	Expert Committee
SODIUM ALGINATE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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