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Sodium Starch Glycolate

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Starch carboxymethyl ether, sodium salt.

DEFINITION

Sodium Starch Glycolate is the sodium salt of a carboxymethyl ether of starch or of a cross-linked carboxymethyl ether of starch. It may contain NMT 7.0% of Sodium Chloride. The pH and assay requirements for Type A and Type B are set forth in the accompanying table.

Type	pH		% Sodium, Combined as Sodium Starch Glycolate	
	Min.	Max.	Min.	Max.
A	5.5	7.5	2.8	4.2
B	3.0	5.0	2.0	3.4

IDENTIFICATION

Change to read:

- †A. ▲SPECTROSCOPIC IDENTIFICATION TESTS ‹197›, *Infrared Spectroscopy*: 197K▲ (CN 1-MAY-2020)

[NOTE—Disregard any peaks at about 845, 1285, and 1305 cm^{−1}, which are attributed to the presence of citrate.]

- †B. An acidified solution of it is colored blue to violet by the addition of iodine and potassium iodide TS 1.
- †C.
Potassium pyroantimonate solution: Dissolve 2 g of potassium pyroantimonate in 85 mL of hot water. Cool quickly, and add 10 mL of a solution of potassium hydroxide (3 in 20). Allow to stand for 24 h, filter, and dilute with water to 100 mL.
Analysis: To a 2-mL portion of the *Sample solution* prepared for the test for *Limit of Iron*, add 2 mL of 15% potassium carbonate, and heat to boiling. No precipitate is formed. Add 4 mL of *Potassium pyroantimonate solution*, and heat to boiling. Allow to cool in ice water and, if necessary, rub the inside of the test tube with a glass rod.
Acceptance criteria: A dense precipitate is formed.
- †D. Sodium Starch Glycolate imparts an intense yellow color to a nonluminous flame.

ASSAY

• PROCEDURE

Sample: 1 g
Analysis: Transfer the *Sample* to a conical flask, add 20 mL of 80% alcohol, stir for 10 min, and filter. Repeat the extraction until the chloride has been completely extracted, as shown by a test with silver nitrate. Dry the insoluble portion at 105° to constant weight, and transfer an accurately weighed portion (700 mg) of the dried 80% alcohol-insoluble portion to a suitable flask. Add 80 mL of glacial acetic acid, and heat the mixture under reflux on a boiling water bath for 2 h. Cool to room temperature, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically.
Calculate the percentage of sodium combined in the form of sodium starch glycolate:

Result = 100 × 22.99 × V × (N/W)

V = volume of perchloric acid consumed (mL)

N = normality of the perchloric acid

W = weight of the dried alcohol-insoluble residue taken for the Assay (mg)

Acceptance criteria: 2.8%–4.2% for Type A; 2.0%–3.4% for Type B

OTHER COMPONENTS

• LIMIT OF SODIUM CHLORIDE

Sample: 500 mg of Sodium Starch Glycolate

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N silver nitrate VS

Endpoint detection: Potentiometric

Electrodes

Indicator: Suitable silver-based

Reference: Double junction electrode containing a 10% potassium nitrate filling solution in the outer jacket, and a standard filling solution in the inner jacket

Analysis: Transfer the *Sample* to a beaker, and suspend in 100 mL of water. Add 1 mL of nitric acid. Titrate with the *Titrant*. Each mL of 0.1 N silver nitrate is equivalent to 5.844 mg of sodium chloride.

Acceptance criteria: NMT 7.0%

• LIMIT OF SODIUM GLYCOLATE

[NOTE—Conduct this test without exposure to daylight. Use low-actinic glassware.]

Solution A: 0.1 mg/mL of 2,7-dihydroxynaphthalene in sulfuric acid; allow to stand until decolorized, and use within 2 days.

Standard solution: Transfer 310 mg of glycolic acid, previously dried over phosphorus pentoxide in a desiccator at room temperature overnight, to a 500-mL volumetric flask. Dissolve in and dilute with water to volume. Transfer 5.0 mL of this solution to a 100-mL beaker, add 4 mL of 6 N acetic acid, and allow to stand for about 30 min. Add 50 mL of acetone and 1 g of sodium chloride, mix, and pass through fast filter paper moistened with acetone into a 100-mL volumetric flask. Rinse the beaker and the filter paper with acetone. Combine the filtrate and washings, dilute with acetone to volume, and mix. Allow to stand for 24 h without shaking. Use the clear supernatant as the *Standard solution*.

Sample solution: Transfer 200 mg to a 100-mL beaker. Add 4 mL of 6 N acetic acid and 5 mL of water. Stir until dissolution is complete (about 10 min). Add 50 mL of acetone and 1 g of sodium chloride, mix, and pass through fast filter paper moistened with acetone into a 100-mL volumetric flask. Rinse the beaker and filter paper with acetone. Combine the filtrate and washings, dilute with acetone to volume, and mix. Allow to stand for 24 h without shaking. Use the clear supernatant as the *Sample solution*.

Analysis: Treat the *Sample solution* and the *Standard solution* as follows. Heat 2.0 mL of the solution on a water bath for 20 min to remove the acetone. Cool to room temperature. Add 20.0 mL of *Solution A* to the solution under test, mix, and heat on a water bath for 20 min. Cool under running water, and quantitatively transfer to a 25-mL volumetric flask. Maintain the flask under running water, and dilute with sulfuric acid to volume. Within 10 min, determine the absorbance of the solution at 540 nm with a suitable spectrophotometer, using water as the blank.

Acceptance criteria: The absorbance of the *Sample solution* is NMT that of the *Standard solution* (2.0%).

IMPURITIES

• LIMIT OF IRON

Standard solution: Dissolve 863.4 mg of ferric ammonium sulfate $[\text{FeNH}_4(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}]$ in water, add 25 mL of 2 N sulfuric acid, dilute with water to 500.0 mL, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask, dilute with water to volume, and mix. Pipet 5 mL of this solution into a 100-mL volumetric flask, dilute with water to volume, and mix. This solution contains the equivalent of 1.0 µg/mL of iron.

Sample solution: Place 2.5 g in a silica or platinum crucible, and add 2 mL of 10 N sulfuric acid. Heat on a water bath, then cautiously raise the temperature progressively over an open flame. Ignite, preferably in a muffle furnace, at $600 \pm 25^\circ$. Continue heating until all black particles have disappeared. Cool, add a few drops of 2 N sulfuric acid, and heat and ignite as above. Add a few drops of 2 M ammonium carbonate, evaporate to dryness, and ignite as above. Cool, dissolve the residue in 50 mL of water, and mix.

[NOTE—Reserve a portion of this solution for *Identification* test C.]

Analysis: Treat the *Sample solution* and the *Standard solution* as follows. Transfer 10 mL of the solution to a suitable beaker, add 2 mL of citric acid solution (1 in 5) and 0.1 mL of thioglycolic acid, and mix. Render the solution alkaline, using litmus paper as an external indicator, by the addition of ammonium hydroxide. Dilute with water to 20 mL, and mix. Allow the solutions to stand for 5 min.

Acceptance criteria: The color of the solution from the *Sample solution* is a shade of pink no deeper than that of the solution from the *Standard solution* (0.002%).

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS (61)**, and **TESTS FOR SPECIFIED MICROORGANISMS (62)**: It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.
- **pH (791)**: Disperse 1 g in 30 mL of water. The pH of the resulting suspension is either 5.5–7.5 for Type A or 3.0–5.0 for Type B.
- **LOSS ON DRYING (731)**.
Analysis: Dry at 130° for 90 min.
Acceptance criteria: NMT 10.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, preferably protected from wide variations in temperature and humidity, which may cause caking.
- **LABELING:** Label it to indicate the botanical source of the starch from which it was derived, the cross-linking agent (if used), the pH range, and whether it is Type A or Type B.
- **USP REFERENCE STANDARDS (11)**.
[USP Sodium Starch Glycolate Type A RS](#)
[USP Sodium Starch Glycolate Type B RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SODIUM STARCH GLYCOLATE	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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