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Propylene Glycol Alginate

DEFINITION

Propylene Glycol Alginate is a propylene glycol ester of alginic acid. Each gram yields NLT 0.16 and NMT 0.20 g of carbon dioxide, calculated on the dried basis.

IDENTIFICATION

• A.

Sample solution: Place 20 mL of the saponified solution obtained in the determination of *Esterified Carboxyl Groups* in a 250-mL conical flask. Add 50 mL of a solution of periodic acid (1 in 50), swirl, and allow to stand for 30 min. Add 2 g of potassium iodide, titrate with sodium thiosulfate TS to a faint yellow color, dilute the mixture with water to 200 mL, and mix to obtain the *Sample solution* for *Identification* test A and *Identification* test B.

Modified Schiff's reagent: Dissolve 200 mg of rosaniline hydrochloride ($C_{20}H_{20}ClN_3$) in 120 mL of hot water. Cool, add 2 g of sodium bisulfite ($NaHSO_3$), followed by 2 mL of hydrochloric acid, and dilute with water to 200 mL. [NOTE—Store this solution in a brown bottle at 15° or lower.]

Analysis: To 10 mL of the *Sample solution* add 5 mL of hydrochloric acid and 10 mL of *Modified Schiff's reagent*.

Acceptance criteria: A blue to blue-violet color, due to formaldehyde, develops in about 20 min.

• B.

Analysis: To 10 mL of the *Sample solution* prepared in *Identification* test A add 1 mL of a saturated solution of piperazine and 0.5 mL of sodium nitroferricyanide TS.

Acceptance criteria: A green color, due to acetaldehyde, develops.

ASSAY

• CONTENT OF ALGINATE

Analysis: Proceed as directed for *Procedure* in [Alginates Assay \(311\)](#), without preliminary drying of the Propylene Glycol Alginate.

Acceptance criteria: 0.16–0.20 g of carbon dioxide/g of Propylene Glycol Alginate, calculated on the dried basis

OTHER COMPONENTS

• FREE CARBOXYL GROUPS

Sample: 1 g

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N sodium hydroxide VS

Endpoint detection: Potentiometric

Analysis: Transfer the *Sample* to a 600-mL beaker. Dissolve in 200 mL of water, stirring by mechanical means for NLT 30 min. Titrate with 0.1 N sodium hydroxide VS to a pH of 7.0.

Calculate the weight, in g, of free carboxyl groups in the *Sample* taken:

$$\text{Result} = [(V \times M_r \times N)/W] \times F$$

V = *Titrant* volume consumed (mL)

M_r = mEq of CO_2 , 44 mg/mEq

N = actual normality of the *Titrant* (mEq/mL)

W = *Sample* weight (g)

F = conversion factor, 10^{-3} g/mg

Acceptance criteria: The weight of free carboxyl groups found, calculated on the dried basis, is NMT 35% of the weight of carbon dioxide yielded by an equal weight of specimen in the Assay.

• **ESTERIFIED CARBOXYL GROUPS**

Sample solution: The solution obtained in the test for *Free Carboxyl Groups*

Analysis: Transfer the *Sample solution* with the aid of water to a 1000-mL conical flask. Add phenolphthalein TS and 50.0 mL of 0.1 N sodium hydroxide VS, insert a stopper in the flask, mix, and allow to stand for 30 min at ambient temperature. Titrate the excess sodium hydroxide with 0.1 N hydrochloric acid VS to a faint pink endpoint. Transfer the solution with the aid of water to a 600-mL beaker, and complete the titration to a pH of 7.0, determining the endpoint potentiometrically.

Calculate the weight, in g, of esterified carboxyl groups in the weight, W , in g, of the specimen taken:

$$\text{Result} = [(V \times M_r \times N)/W] \times F$$

V = volume of 0.1 N sodium hydroxide consumed (mL)

M_r = mEq of CO_2 , 44 mg/mEq

N = actual normality of 0.1 N sodium hydroxide (mEq/mL)

W = specimen weight (g)

F = conversion factor, 10^{-3} g/mg

Acceptance criteria: The weight of esterified carboxyl groups found, calculated on the dried basis, is 40%–85% of the weight of carbon dioxide yielded by an equal weight of specimen in the Assay.

IMPURITIES

Change to read:

- **▲** [ARSENIC \(211\), Procedures, Procedure 2](#) **▲** (CN 1-JUN-2023) : 3 ppm

Change to read:

- **▲** [LEAD \(251\), Procedures, Procedure 1](#) **▲** (CN 1-JUN-2023)

Standard solution: 5 mL of *Diluted Standard Lead Solution*

Test preparation: Add 1.0 g to 20 mL of nitric acid in a 250-mL conical flask, mix, and heat carefully until the specimen is dissolved. Continue the heating until the volume is reduced to 7 mL. Cool rapidly to room temperature, transfer to a 100-mL volumetric flask, dilute with water to volume, and mix. Use a 50-mL portion.

Analysis: Proceed as directed in the chapter, using 15 mL of ammonium citrate solution, 3 mL of potassium cyanide solution, and 0.5 mL of hydroxylamine hydrochloride solution for the test. After the first dithizone extractions, wash the combined chloroform layers with 5 mL of water, discarding the water layer and continuing in the usual manner by extracting with 20 mL of 0.2 N nitric acid.

Acceptance criteria: A 50.0-mL portion of this solution contains NMT 5 µg of lead (corresponding to NMT 10 ppm of Pb).

SPECIFIC TESTS

- [MICROBIAL ENUMERATION TESTS \(61\)](#) and [TESTS FOR SPECIFIED MICROORGANISMS \(62\)](#): The total bacterial count does not exceed 200 cfu/g, and the tests for *Salmonella* species and *Escherichia coli* are negative.

- [LOSS ON DRYING \(731\)](#): Dry a sample at 105° for 4 h: it loses NMT 20.0% of its weight.

• **ASH**

Sample: 3 g

Analysis: Weigh the *Sample* in a tared crucible, and incinerate at $650 \pm 25^\circ$ until free from carbon. Cool in a desiccator, weigh, and determine the weight of the ash.

Acceptance criteria: NMT 10.0% on the dried basis

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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