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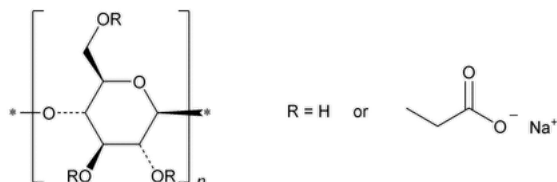
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Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium



Sodium salts of polymers containing substituted anhydroglucose units with the general formula: $[C_6H_7O_2(OH)_x(OCH_2COONa)_y]_n$

where n is the degree of polymerization;

y is the degree of substitution;

x is between 1.50 and 2.80;

y is between 0.20 and 1.50;

and $x + y = 3.0$

Carboxymethyl cellulose, sodium, partially hydrolyzed enzymatically.

DEFINITION

Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium is the sodium salt of a polycarboxymethyl ether of cellulose, which has been partially hydrolyzed by enzymatic treatment with food grade *Trichoderma reesei cellulase*. Its degree of substitution is NLT 0.20 and NMT 1.50, corresponding to a sodium (Na) content of NLT 2.6% and NMT 12.2%, calculated on the dried basis.

IDENTIFICATION

- **A.** Vigorously shake a 0.1% solution of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium: no layer of foam appears.
- **B.** To 5 mL of a 0.5% solution of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium add 5 mL of a 5% solution of copper or aluminium sulfate: a precipitate appears.
- **C.** Add 0.5 g of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium to 50 mL of water, while stirring, to produce a uniform dispersion. Continue stirring until a clear solution of 1% is produced. Dilute 1 mL of this solution with 1 mL of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 mL of sulfuric acid, so that it forms a lower layer: a red-purple color develops at the interface.
- **D.** [IDENTIFICATION TESTS—GENERAL, Sodium \(191\)](#): A portion of the 1% solution obtained from Identification test C meets the requirements.
- **E.** It meets the requirements of the test for *Viscosity*.

ASSAY

• DEGREE OF SUBSTITUTION

Sample: 2.0 g of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium

Analysis: Ignite a clean and dry quartz crucible with a Bunsen burner, cool to room temperature in a desiccator, and weigh the crucible accurately. Transfer the *Sample* to the crucible. Carefully ignite on a small flame for about 10 min, and make sure that the *Sample* does not burn or excessively glow. Cool, and moisten the residue with 3–5 mL of sulfuric acid. Heat the crucible cautiously until the fuming is complete, and heat further until the *Sample* turns grayish white. Place the crucible in an oven at about 600°, until no black spots are visible. Cool the crucible in a desiccator to room temperature, and weigh. Place the crucible again in an oven at about 600° for 1 h, cool the crucible to room temperature in a desiccator, and weigh. This last step is repeated until a constant weight is achieved.

Calculate the percentage of sodium, P_{Na} , in the portion of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium taken:

$$\text{Result} = 100 \times N_{Na} \times A_{Na} \times (W_2 - W_1) / \{M_r \times W[(100 - \text{LOD})/100]\}$$

N_{Na} = number of sodium atoms/molecule of sodium sulfate, 2

A_{Na} = atomic weight of sodium, 22.99

W_2 = weight of the crucible with ash residue (g)

W_1 = weight of the crucible (g)

M_r = molecular weight of sodium sulfate, 142.04

W = weight of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium taken (g)

LOD = Loss on Drying value of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium (%)

Calculate the *Degree of Substitution* (DS):

$$\text{Result} = M_{r1} \times (P_{Na} - P_{NaCl} - P_{NaG}) / \{100 \times A_{Na} - [(M_{r2} - A_H) \times (P_{Na} - P_{NaCl} - P_{NaG})]\}$$

M_{r1} = molar mass of one glucose unit, 162.14

P_{NaCl} = percentage of sodium chloride obtained in the test for *Limit of Sodium Chloride and Sodium Glycolate*

P_{NaG} = percentage of sodium glycolate obtained in the test for *Limit of Sodium Chloride and Sodium Glycolate*

A_{Na} = atomic weight of sodium, 22.99

M_{r2} = molar mass of one sodium carboxymethyl unit (CH_2COONa), 81.03

A_H = atomic weight of hydrogen, 1.01

Acceptance criteria: NLT 0.20 and NMT 1.50 carboxymethyl groups (CH_2COOH)/anhydroglucose unit on the dried basis

IMPURITIES

Inorganic Impurities

• LIMIT OF LEAD

Nitric acid solution: Dilute 10 mL of nitric acid with 20 mL of water. Boil this solution to remove nitrous fumes, and allow it to cool to room temperature.

Lead standard stock solution: Dissolve 1.60 g of lead nitrate ($\text{Pb}(\text{NO}_3)_2$) in about 30 mL of *Nitric acid solution* in a 1000-mL volumetric flask, dilute with water to volume, and mix. At 20°, transfer 10.0 mL of this lead solution to a 500-mL volumetric flask, and dilute with water to volume. The *Lead standard stock solution* contains 20 µg/mL of Pb.

Standard solutions: Transfer 0, 1, 2, 3, 4, and 5 mL of the *Lead standard stock solution* to six identical 100-mL volumetric flasks, and add 50 mL of water to each flask. To each flask, add 8 mL of sulfuric acid and 10 mL of hydrochloric acid, and mix well. After complete dissolution, dilute each flask with water to volume, and mix. Transfer 1 mL of each solution to a separate 50-mL volumetric flask, and dilute with water to a final concentration of 0, 4, 8, 12, 16, and 20 µg/L of Pb, respectively.

Sample solution: Transfer 1 g of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium to a 100-mL beaker, and add 5 mL of 30% hydrogen peroxide. While stirring, add 50 mL of water to the solution, and heat the beaker on a hot plate at 50°, until all solids are dissolved. Quantitatively transfer this solution to a 100-mL volumetric flask, add 300 µL of nitric acid, dilute with water to volume, and mix.

Blank solution: Prepare as directed in the *Sample solution*, but omit the test specimen.

Spectrometric conditions

(See [Atomic Absorption Spectroscopy \(852\)](#))

Mode: Graphite furnace atomic absorption spectrophotometer, equipped with a lead hollow-cathode lamp and an adequate means of background correction.

Analytical wavelength: Lead emission line of 283.3 nm

Analysis

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

Concomitantly determine the absorbances of the *Samples*. Optimize the instrument program for lead as recommended by the manufacturer. The strongest *Standard solution* is aspirated to optimize the instrument settings to give a full-scale reading on the detector. Correct the area responses of all *Sample solution* and *Standard solutions* for the *Blank solution* area response. Generate the appropriate lead calibration curve, and determine the lead concentration, C , in µg/L, in the *Sample solution*.

Calculate the content of lead, in µg, in each g of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium taken:

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

V = volume of the *Sample solution*, 0.1 L

W = weight of Enzymatically-Hydrolyzed Carboxymethylcellulose Sodium taken to prepare the *Sample solution* (g)

Acceptance criteria: NMT 3 µg/g of lead.

• LIMIT OF SODIUM CHLORIDE AND SODIUM GLYCOLATE

Sodium Chloride

Ferric solution: Dissolve 20 g of ferric ammonium sulfate ($\text{FeNH}_4(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$) in a 100-mL volumetric flask containing 80 mL of water, add 0.3 mL of 10 N nitric acid (dilute 600 mL of nitric acid with water to 1000 mL), dilute with water to volume, and mix.