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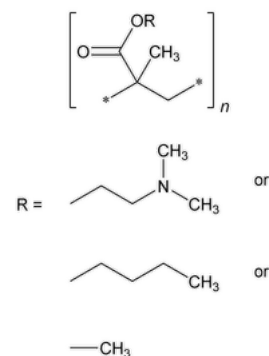
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Amino Methacrylate Copolymer

Ratio: $\text{CH}_2\text{CH}_2\text{N}(\text{CH}_3)_2 : \text{C}_4\text{H}_9 : \text{CH}_3 = 2:1:1$

Poly((2-dimethylaminoethyl)methacrylate, butyl methacrylate, methyl methacrylate) (2:1:1);

N,N-Dimethylaminoethyl methacrylate–butyl methacrylate–methyl methacrylate copolymer (2:1:1)

CAS RN®: 24938-16-7.

DEFINITION

Amino Methacrylate Copolymer is a polymerized copolymer of (2-dimethylaminoethyl) methacrylate, butyl methacrylate, and methyl methacrylate. It contains NLT 20.8% and NMT 25.5% of dimethylaminoethyl groups ($\text{C}_4\text{H}_{10}\text{N}$), calculated on the dried basis.

IDENTIFICATION

Change to read:

• **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

• **B.**

Sample solution: 1 mL of the *Sample solution* in the test for *Viscosity*

Analysis: Pour the *Sample solution* onto a glass plate, and allow the solvent to evaporate.

Acceptance criteria: A clear, colorless film results.

ASSAY

PROCEDURE

Sample: 200 mg

Blank: 4 mL of water and 96 mL of glacial acetic acid

Titrimetric system

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

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in a mixture of 4 mL of water and 96 mL of glacial acetic acid. Titrate with the *Titrant* to a potentiometric endpoint. Perform a blank determination.

Calculate the percentage of dimethylaminoethyl groups ($\text{C}_4\text{H}_{10}\text{N}$) in the portion of the sample taken:

$$\text{Result} = \left\{ \frac{(V_S - V_B) \times N \times F}{W} \right\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)

V_B = *Titrant* volume consumed by the *Blank* (mL)

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

F = equivalency factor, 72.1 mg/mEq

W = Sample weight (mg)

Acceptance criteria: 20.8%–25.5% on the dried basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• **LIMIT OF BUTYL METHACRYLATE AND METHYL METHACRYLATE**

Buffer: 8.9 g/L of anhydrous dibasic sodium phosphate and 8.5 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 2.0. This is pH 2.0 phosphate buffer (0.0625 M).

Mobile phase: Methanol and *Buffer* (55:45)

Diluent: Acetonitrile and *Buffer* (40:60)

Standard solution: Dissolve 20 mg of butyl methacrylate and 10 mg of methyl methacrylate in 3 mL of *n*-butanol. Dilute with *Diluent* to 10 mL. Dilute 1.0 mL of this solution with *Diluent* to 250.0 mL, and mix. This solution contains about 8 µg/mL of butyl methacrylate and 4 µg/mL of methyl methacrylate.

Sample solution: 20 mg/mL of Amino Methacrylate Copolymer in *Diluent*

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 205 nm

Column: 4.6-mm × 12-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 10 between butyl methacrylate and methyl methacrylate

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each monomer in the portion of Amino Methacrylate Copolymer taken:

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

r_U = peak response of each monomer (butyl methacrylate or methyl methacrylate) from the *Sample solution*

r_S = peak response of each monomer (butyl methacrylate or methyl methacrylate) from the *Standard solution*

C_S = concentration of each monomer (butyl methacrylate or methyl methacrylate) in the *Standard solution* (µg/mL)

C_U = concentration of Amino Methacrylate Copolymer in the *Sample solution* (mg/mL)

F = conversion factor, 10^{-3} mg/µg

Acceptance criteria: NMT 0.1% for each monomer

• **LIMIT OF 2-DIMETHYLAMINOETHYL METHACRYLATE**

Buffer: 3.4 g/L of monobasic potassium phosphate. This is the monobasic potassium phosphate solution (0.025 M).

Mobile phase: Tetrahydrofuran and *Buffer* (75:25)

Standard solution: 8 µg/mL of 2-dimethylaminoethyl methacrylate in tetrahydrofuran

Sample solution: 20 mg/mL of Amino Methacrylate Copolymer in tetrahydrofuran

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 12-cm; packing L8

Flow rate: 2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 2-dimethylaminoethyl methacrylate in the portion of Amino Methacrylate Copolymer taken: