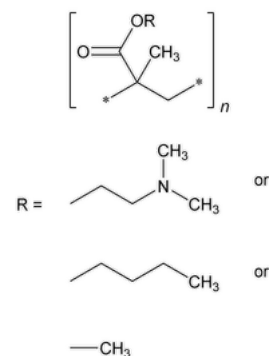


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## Amino Methacrylate Copolymer



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:

- $r_U$  = peak response of 2-dimethylaminoethyl methacrylate from the *Sample solution*
- $r_S$  = peak response of 2-dimethylaminoethyl methacrylate from the *Standard solution*
- $C_S$  = concentration of 2-dimethylaminoethyl 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%

**SPECIFIC TESTS**

• **VISCOSITY—ROTATIONAL METHODS (912).**

**Sample solution:** Dissolve 12.5 g in a mixture of 35.0 g of acetone and 52.5 g of isopropyl alcohol. [NOTE—Reserve a portion of this solution for the *Color of Solution* test.]

**Analysis:** Equip a suitable rotational viscometer with an adapter comprising a cylindrical spindle rotating within an accurately machined chamber (or tube).<sup>1</sup>Pipet the *Sample solution* in the specified volume, which is recommended by the instrument manufacturer, into the chamber (or tube), and ensure that the temperature of the test specimen is at  $20 \pm 0.1^\circ$ . The cylindrical spindle rotates at the value of rpm, which corresponds to a rate of shear of approximately  $37\text{ s}^{-1}$ .<sup>2</sup> Measure the apparent viscosity following the instrument manufacturer's directions.

**Acceptance criteria:** Viscosity, 3–6 mPa · s

• **COLOR OF SOLUTION**

**Sample solution:** Use the *Sample solution* prepared in the test for *Viscosity*.

**Instrumental conditions**

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

**Mode:** Vis

**Analytical wavelength:** 420 nm

**Cell:** 1 cm

**Analysis:** Determine the absorbance of the *Sample*, using water as the blank.

**Acceptance criteria:** NMT 0.300

• **LOSS ON DRYING (731).**

**Analysis:** Dry a sample at  $110^\circ$  for 3 h.

**Acceptance criteria:** NMT 2.0%

**ADDITIONAL REQUIREMENTS**

• **PACKAGING AND STORAGE:** Preserve in tight containers, and store at a temperature below  $30^\circ$ .

• **USP REFERENCE STANDARDS (11).**

[USP Amino Methacrylate Copolymer RS](#)

<sup>1</sup> A commercial device is available from Brookfield as an ultra-low (UL) viscosity adapter. The adapter comprises a 0.4-cm diameter shaft, an accurately machined chamber (or tube) with an internal diameter of 2.8 cm and a depth of 13.5 cm, and a cylindrical spindle 2.5 cm in diameter and 9.1 cm in height.

<sup>2</sup> For the Brookfield UL adapter, the cylindrical spindle rotates at 30 rpm, which corresponds to a rate of shear of approximately  $37\text{ s}^{-1}$ .

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

Topic/Question	Contact	Expert Committee
AMINO METHACRYLATE COPOLYMER	<a href="#">Documentary Standards Support</a>	CE2020 Complex Excipients

**Chromatographic Database Information:** [Chromatographic Database](#)

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