

Printed on: Fri Dec 26 2025, 08:34:24 am

Printed by: Rani Maulani

Status: Currently Official on 26-Dec-2025

Official Date: Official as of 01-May-2020

Document Type: NF Monographs

DocId: GUID-93806F87-1D09-4385-8B6B-4C5889932273_4_en-US

DOI: https://doi.org/10.31003/USPNF_M2676_04_01

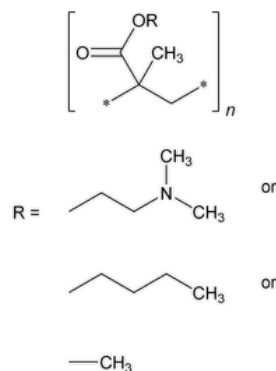
DOI Ref: 7u2cq

Printed from: https://online.uspnf.com/uspnf/document/1_GUID-93806F87-1D09-4385-8B6B-4C5889932273_4_en-US

© 2025 USPC

Do not distribute

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:

$$\text{Result} = \left\{ \left[(V_s - V_b) \times N \times F \right] / W \right\} \times 100$$

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:

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

 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).¹ 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 s^{-1} .² 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° for 3 h.**Acceptance criteria:** NMT 2.0%**ADDITIONAL REQUIREMENTS**• **PACKAGING AND STORAGE:** Preserve in tight containers, and store at a temperature below 30° .• **USP Reference Standards (11).**[USP Amino Methacrylate Copolymer RS](#)

- ¹ 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.
- ² For the Brookfield UL adapter, the cylindrical spindle rotates at 30 rpm, which corresponds to a rate of shear of approximately 37 s⁻¹.

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

Topic/Question	Contact	Expert Committee
AMINO METHACRYLATE COPOLYMER	Documentary Standards Support	EXC22025 Excipient Monographs 2
REFERENCE STANDARDS SUPPORT	RS Technical Services RSTECH@usp.org	EXC22025 Excipient Monographs 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 34(2)

Current DocID: GUID-93806F87-1D09-4385-8B6B-4C5889932273_4_en-US
DOI: <https://doi.org/10.31003/USPNF.M2676.04.01>
DOI ref: [7u2cq](#)

OFFICIAL