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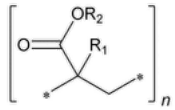
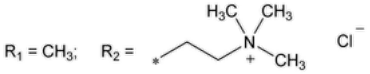
Ammonio Methacrylate Copolymer



$R_1 = CH_3$; $R_2 = CH_3$ or

$R_1 = H$; $R_2 = C_2H_5$ or



Ratio of ethyl acrylate groups to methyl methacrylate groups to trimethylammonioethyl methacrylate groups is about 1:2:0.2 as being Type A or 1:2:0.1 as being Type B.

Poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) (1:2:0.2);

Ethyl acrylate–methyl methacrylate–trimethylammonioethyl methacrylate chloride copolymer (1:2:0.2);

Poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) (1:2:0.1);

Ethyl acrylate–methyl methacrylate–trimethylammonioethyl methacrylate chloride copolymer (1:2:0.1) CAS RN®: 33434-24-1.

DEFINITION

Ammonio Methacrylate Copolymer is a polymerized copolymer of ethyl acrylate, methyl methacrylate, and a low content of methacrylic acid ester with quaternary ammonium groups (trimethylammonioethyl methacrylate chloride). The *Assay* requirements differ for the two types as set forth in the accompanying table.

	Ammonio Methacrylate Units, Dried Basis (%)	
Type	**Min.**	**Max.**
A	8.85	11.96
B	4.48	6.77

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

• **B.** Meets the requirements of the *Assay*

ASSAY

• **Procedure**

Sample: 1 g of Ammonio Methacrylate Copolymer Type A, or 2 g of Type B, previously dried

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis

Sample: *Sample*

Dissolve the *Sample* in 75 mL of glacial acetic acid at about 50° within 30 min. After the solution cools down to room temperature, add 25 mL of 0.6% cupric acetate in glacial acetic acid. Titrate this solution and a blank, and make any necessary corrections. Each mL of 0.1 N perchloric acid is equivalent to 20.772 mg of ammonio methacrylate ($C_9H_{18}ClNO_2$) units.

Acceptance criteria

Type A: 8.85%–11.96%

Type B: 4.48%–6.77%

IMPURITIES

Inorganic Impurities

- **Residue on Ignition ⟨281⟩:** NMT 0.1%

Organic Impurities

- **Procedure: Limit of Monomers**

Sodium perchlorate solution: 35 mg/mL of sodium perchlorate ($NaClO_4 \cdot H_2O$)

Mobile phase: Dilute phosphoric acid with water to obtain a solution with a pH of 2.0. Mix 4 volumes of this solution with 1 volume of methanol.

Standard stock solution: 1.6 mg/mL of ethyl acrylate and 0.2 mg/mL of methyl methacrylate in methanol

Standard solution: Dilute 1 mL of the *Standard stock solution* with methanol to 100 mL. Add 10 mL of this solution to 5 mL of the *Sodium perchlorate solution*. This solution contains about 10.67 µg/mL of ethyl acrylate and 1.33 µg/mL of methyl methacrylate.

Sample solution: Dissolve 5 g of Ammonio Methacrylate Copolymer in methanol, and dilute with the same solvent to 50 mL. Add 5 mL of the *Sodium perchlorate solution* dropwise to 10 mL of this solution while continuously stirring. Remove the precipitated polymer by centrifugation. Use the clear supernatant. Calculate the concentration of Ammonio Methacrylate Copolymer, in mg/mL, as C_U.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 202 nm

Column: 4.6-mm × 12-cm; packing L1

Flow rate: 2 mL/min

Injection size: 50 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for ethyl acrylate and methyl methacrylate are 1.00 and 1.14, respectively.]

Suitability requirements

Resolution: NLT 1.0 between the pair of analytes

Relative standard deviation: NMT 5.0% for each analyte

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethyl acrylate (or methyl methacrylate) in the portion of Ammonio Methacrylate Copolymer taken:

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

r_U = peak response of ethyl acrylate (or methyl methacrylate) from the *Sample solution*

r_S = peak response of ethyl acrylate (or methyl methacrylate) from the *Standard solution*

C_S = concentration of ethyl acrylate (or methyl methacrylate) in the *Standard solution* (µg/mL)

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

F = conversion factor, 10^{-3} mg/µg

Acceptance criteria

Ethyl acrylate: NMT 100 ppm

Methyl methacrylate: NMT 50 ppm

SPECIFIC TESTS

- **Loss on Drying ⟨731⟩:** Dry a sample in a vacuum at 80° for 5 h: it loses NMT 3.0% of its weight.

- **Viscosity—Rotational Methods ⟨912⟩**

Sample solution: Place 52.5 g of isopropyl alcohol and 35.0 g of acetone in a conical flask with a ground-glass joint. Add a quantity of Ammonio Methacrylate Copolymer, equivalent to 12.5 g of solids on the dried basis, while stirring until the polymer has dissolved completely.

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 ± 0.1°. 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: 1–15 mPa · s

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at a temperature not exceeding 30°.
- **Labeling:** Label it to state whether it is Type A or Type B.
- **USP Reference Standards** ⟨11⟩

USP Ammonio Methacrylate Copolymer, Type A RS
Poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) (1:2:0.2);
Ethyl acrylate–methyl methacrylate–trimethylammonioethyl methacrylate chloride copolymer (1:2:0.2).

USP Ammonio Methacrylate Copolymer, Type B RS
Poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) (1:2:0.1);
Ethyl acrylate–methyl methacrylate–trimethylammonioethyl methacrylate chloride copolymer (1:2:0.1).

[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
AMMONIO METHACRYLATE COPOLYMER	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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