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Ammonio Methacrylate Copolymer Dispersion

DEFINITION

Ammonio Methacrylate Copolymer Dispersion is an aqueous dispersion of Ammonio Methacrylate Copolymer Type A or B in water. It may contain suitable antimicrobial preservatives and alkalizing agents. The *Assay* requirements differ for the two types, as set forth in the accompanying table.

	Ammonio Methacrylate Units, Dried Basis (%)	
Type	**Min.**	**Max.**
A	10.18	13.73
B	6.11	8.26

IDENTIFICATION

Change to read:

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

Sample: Residue obtained in the test for *Loss on Drying*

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Sample: Dry under vacuum 2 g of Ammonio Methacrylate Copolymer Dispersion Type A, or 4 g of Ammonio Methacrylate Copolymer Dispersion Type B, at 90° for 30 min.

Blank: 75 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 75 mL of glacial acetic acid at about 50°, within about 30 min. After the solution has cooled down, add 25 mL of 0.6% cupric acetate solution in glacial acetic acid. Titrate this solution with the *Titrant*. Perform a blank determination. Calculate the percentage of ammonio methacrylate ($C_9H_{18}ClNO_2$) units in the portion of the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

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, 207.72 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria

Type A: 10.18%–13.73%

Type B: 6.11%–8.26%

IMPURITIES

• **Residue on Ignition** ⟨281⟩

Analysis: Using mild heating conditions (e.g., steam bath, sand bath, etc.) to avoid loss of material, evaporate the dispersion to dryness before ignition.

Acceptance criteria: NMT 0.5% calculated on the undried dispersion basis

- **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 having a pH of 2.0. Mix four volumes of this solution with one volume of methanol, filter, and degas.

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 *Sodium perchlorate solution*.

Sample solution: Dissolve 5 g of Dispersion in methanol, and dilute with the same solvent to 50 mL. Add 5 mL of *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 Dispersion, 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 volume: 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%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethyl acrylate and methyl methacrylate in the portion of Dispersion 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 = nominal concentration of Dispersion in the *Sample solution* (mg/mL)

F = conversion factor, 10^{-3} mg/µg

Acceptance criteria: NMT 0.002% of methyl methacrylate and NMT 0.008% of ethyl acrylate

SPECIFIC TESTS

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

Analysis: Use a viscometer equipped with a spindle having a cylinder 1.88 cm in diameter and 6.51 cm high attached to a shaft 0.32 cm in diameter. The distance from the top of the cylinder to the lower tip of the shaft is 0.75 cm, and the immersion depth is 8.15 cm. Adjust the temperature to 20 ± 0.10°. With the spindle rotating at 30 rpm, immediately record the scale reading. Multiply the scale reading by the constant for the viscometer spindle and speed used to obtain the viscosity in centipoises.

Acceptance criteria: NMT 100 mPa · s

- **Loss on Drying ⟨731⟩**

Analysis: Dry a sample at 110° for 6 h.

Acceptance criteria: 68.5%–71.5%

- **Coagulum Content**

Sample: 100 g

Analysis: Weigh a stainless steel sieve having 125-µm openings, and filter the *Sample* through it. Wash the sieve with distilled water until a clear filtrate is obtained, and dry the sieve to constant weight at 105°.

Acceptance criteria: The weight of the residue does not exceed 1000 mg, corresponding to NMT 1%.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, at a temperature not exceeding 25° for Type A and not exceeding 30° for Type B. Protect from freezing.

• **Labeling:** Label it to state whether it is Type A or Type B. Label it to indicate the name and quantity of any added antimicrobial preservative or alkalizing agent.

• **USP Reference Standards** ⟨11⟩
USP Ammonio Methacrylate Copolymer, Type A RS
USP Ammonio Methacrylate Copolymer, Type B RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMMONIO METHACRYLATE COPOLYMER DISPERSION	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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