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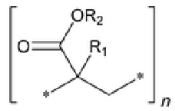
Methacrylic Acid and Ethyl Acrylate Copolymer



	R_1	R_2
	CH_3	H
or	H	C_2H_5

Poly(methacrylic acid, ethyl acrylate);
Methacrylic acid–ethyl acrylate copolymer
CAS RN®: 25212-88-8.

DEFINITION

Methacrylic Acid and Ethyl Acrylate Copolymer consists of methacrylic acid and ethyl acrylate monomers arranged in a random distribution. Methacrylic acid units in Methacrylic Acid and Ethyl Acrylate Copolymer, previously dried, are NLT 46.0% and NMT 50.6%. It may contain suitable surface-active agents.

IDENTIFICATION

Change to read:

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K:** Use ▲USP Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS (USP Methacrylic Acid Copolymer Type C RS)▲ (ERR 1-Jul-2023) for Methacrylic Acid and Ethyl Acrylate Copolymer having a range of 46.0%–50.6% for methacrylic acid units.

• **B.** It meets the requirements of the *Assay*.

ASSAY

• **Procedure**

Sample: 1 g, previously dried

Analysis: Dissolve the *Sample* in 100 mL of neutralized acetone, and titrate with 0.1 N sodium hydroxide VS, determining the endpoint potentiometrically (see *Titrimetry ⟨541⟩*). Each mL of 0.1 N sodium hydroxide is equivalent to 8.609 mg of methacrylic acid ($C_4H_6O_2$) units.

Acceptance criteria: 46.0%–50.6%

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.4%

• **Limit of Methacrylic Acid and Ethyl Acrylate**

Sodium perchlorate solution: 35 mg/mL of sodium perchlorate. This solution has a concentration of 0.25 M.

Mobile phase: Add phosphoric acid dropwise to water to obtain a solution with a pH of 2.0. Prepare a mixture of this acidified water and methanol (80:20), and degas.

Standard solution: Dissolve 0.01 g of methacrylic acid and 0.01 g of ethyl acrylate in 5 mL of butanol, and add methanol to exactly 100 mL. Transfer 1.0 mL of this solution to a 100-mL volumetric flask. Dilute with methanol to volume. Mix 5.0 mL of this solution with 5.0 mL of *Sodium perchlorate solution*. This solution contains about 0.5 µg/mL each of methacrylic acid and ethyl acrylate.

Sample solution: Transfer about 3 g of Methacrylic Acid and Ethyl Acrylate Copolymer to a 50-mL volumetric flask, dilute with methanol to volume, and mix. Add 5.0 mL of this solution dropwise, while continuously stirring, to a beaker that contains 5.0 mL of *Sodium perchlorate solution*. Remove the precipitated polymer to obtain a clear supernatant by centrifugation (e.g., NLT 5000 × *g* for NLT 5 min). Use the clear supernatant.

Chromatographic system

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

Mode: LC

Detector: UV 202 nm

Column: 4.0-mm × 12.5-cm; 7-µm packing L1

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for methacrylic acid and ethyl acrylate are 1.0 and 2.6, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methacrylic acid and ethyl acrylate

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each monomer (methacrylic acid or ethyl acrylate) in the portion of Methacrylic Acid and Ethyl Acrylate Copolymer taken:

$$\text{Result} = (r_U/r_S) \times (C/W) \times V_F \times D \times F \times 100$$

r_U = peak response of the monomer (methacrylic acid or ethyl acrylate) from the *Sample solution*

r_S = peak response of the monomer (methacrylic acid or ethyl acrylate) from the *Standard solution*

C = concentration of the monomer (methacrylic acid or ethyl acrylate) in the *Standard solution* (µg/mL)

W = weight of Methacrylic Acid and Ethyl Acrylate Copolymer taken to prepare the *Sample solution* (g)

V_F = final volume of the *Sample solution*, 10 mL

D = dilution factor for preparation of the *Sample solution*, 10

F = conversion factor, 10^{-6} g/µg

Acceptance criteria: NMT 0.01% for the total amount of monomers

SPECIFIC TESTS

• **VISCOSITY—ROTATIONAL METHODS ⟨912⟩**

Analysis: Place 254.6 g of isopropyl alcohol and 7.9 g of water in a test flask. Add a quantity of Methacrylic Acid and Ethyl Acrylate Copolymer, equivalent to 37.5 g of solids on the dried basis, while stirring by means of a magnetic stirrer. Close the flask, and continue stirring until the polymer has dissolved completely. Adjust the temperature to 20 ± 0.1°. Equip a rotational rheometer[1] following *Method II*. The shear rate under the test condition is NLT 1 s^{-1} and NMT 100 s^{-1}. Validations demonstrate that equivalent viscosity value is also obtained using a rotational viscometer with a cylindrical spindle 1.9 cm in diameter and 6.5 cm high, attached to a shaft 0.3 cm in diameter.[2] The spindle rotates at 30 rpm at an immersion depth of 8.15 cm (see *Method I*). Follow the instrument manufacturer's directions to measure the apparent viscosity.

Acceptance criteria: 100–200 mPa · s, for Methacrylic Acid and Ethyl Acrylate Copolymer with a range of 46.0%–50.6% for methacrylic acid units

• **LOSS ON DRYING ⟨731⟩**

Analysis: Dry at 110° for 6 h.

Acceptance criteria: NMT 5.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers, and store at controlled room temperature.

• **LABELING:** Label it to indicate the range of methacrylic acid units. The labeling also indicates the name and quantity of any added surface-active agent.

Change to read:

• **USP REFERENCE STANDARDS ⟨11⟩**

▲ USP Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS (USP Methacrylic Acid Copolymer Type C RS)▲ (ERR 1-Jul-2023)

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[1] A suitable rheometer is available from Physica Messtechnik GmbH as the Coaxial-Cylinder 27 or the Double-Gap-Cylinder 26.7, or any other equivalent rheometer.

[2] A suitable spindle is available from Brookfield as an LV1 spindle, or the equivalent.

Topic/Question	Contact	Expert Committee
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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