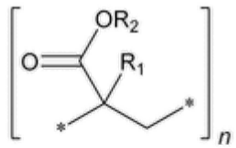
Methacrylic Acid and Ethyl Acrylate Copolymer

(Title for this new monograph—to become official December 1, 2015)

(Prior to December 1, 2015, the current practice of labeling the article of commerce with the name Methacrylic Acid Copolymer, Type C, may be continued. Use of the name Methacrylic Acid and Ethyl Acrylate Copolymer will be permitted as of December 1, 2010, but the use of this name will not be mandatory until December 1, 2015. The 60-month extension will provide the time needed by manufacturers and users to make necessary changes.)



	R_1	R_2
	CH_3	H
or	H	C_2H_5

Poly(methacrylic acid, ethyl acrylate);

Methacrylic acid–ethyl acrylate copolymer [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 are NLT 46.0% and NMT 50.6%, calculated on the dried basis. It may contain suitable surface-active agents.

IDENTIFICATION

- A. Infrared Absorption ⟨ 197K
  Use USP Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS 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% for Methacrylic Acid and Ethyl Acrylate Copolymer on the dried basis

IMPURITIES

Inorganic Impurities

- Residue on Ignition ⟨281⟩ : NMT 0.4%
- Heavy Metals, Method II ⟨231⟩ : NMT 20 ppm

Organic Impurities

- Procedure: 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 having 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 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 analytical column; 7-µm packing L1

  Flow rate: 2 mL/min

  Injection size: 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:

$$\text{Result} = (rU/rS) \times (C/W) \times VF \times D \times F \times 100$$

rU = = monomer (methacrylic acid or ethyl acrylate) peak response from the Sample solution

rS = = monomer (methacrylic acid or ethyl acrylate) peak response 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)

VF = = 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 ⟨ 911

  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 viscometer with an accessory.[1] The shear rate under the test condition is NLT 1 s^{-1} and NMT 100 s^{-1}. 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 : Dry a sample at 110° for 6 h: it loses NMT 5.0% of its weight.

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.
- USP Reference Standards ⟨ 11

  USP Methacrylic Acid and Ethyl Acrylate Copolymer (1:1) RS

  USP Methacrylic Acid Copolymer, Type C RS.

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1 A suitable accessory is available from Brookfield Engineering as the LV1 spindle, a cylindrical spindle 1.9 cm in diameter and 6.5 cm high attached to a shaft 0.3 cm in diameter. The spindle rotates at 30 rpm at an immersion depth of 8.15 cm.

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

Topic/Question	Contact	Expert Committee
Monograph	Robert H. Lafaver, M.S. Scientific Liaison 1-301-816-8335	(EXC2010) Monographs - Excipients

Topic/Question	Contact	Expert Committee
Reference Standards	RS Technical Services 1-301-816-8129 rstech@usp.org	