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Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion

CAS RN®: 9010-88-2.

DEFINITION

Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion is an aqueous dispersion of a copolymer of ethyl acrylate and methyl methacrylate having an average molecular weight of about 800,000. It may contain suitable emulsifying agents.

IDENTIFICATION

Change to read:

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

Analysis: Place 1 drop of Dispersion on a glass plate,[1] and cover the test substance with a water-resistant crystal disk (silver chloride or KRS-5).[2] Gently press on and then remove the crystal disk. Dry the crystal disk at 80° for approximately 15 min.

Acceptance criteria: The IR absorption spectrum of Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion exhibits maxima corresponding to the same wavelengths as those of a similar preparation of USP Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion RS treated in the same manner.

IMPURITIES

Inorganic Impurities

• **Residue on Ignition ⟨281⟩:** Using mild heating conditions (e.g., steam bath, sand bath) to avoid loss of material, evaporate the Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion to dryness before ignition: NMT 0.4% residue is obtained, calculated on the undried basis.

Organic Impurities

• **Procedure: Limit of Monomers**

Solution A: 35 mg/mL of sodium perchlorate

Solution B: Dilute phosphoric acid with water to obtain a solution having a pH of 2.0.

Mobile phase: *Solution B* and methanol (4:1)

Standard solution: Prepare a solution in tetrahydrofuran having a concentration of 2 µg/mL each of ethyl acrylate and methyl methacrylate. To 10.0 mL of this solution add 5.0 mL of *Solution A*, and mix. Dilute 5.0 mL of the mixture with water to 10.0 mL, and mix. The solution contains a concentration of 0.67 µg/mL each of ethyl acrylate and methyl methacrylate.

Sample stock solution: 20 mg/mL of Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion in tetrahydrofuran

Sample solution: To 5.0 mL of *Solution A* add 10.0 mL of *Sample stock solution*, dropwise, while stirring continuously. Centrifuge, and filter the clear supernatant. Dilute 5.0 mL of the clear supernatant with water to 10.0 mL, and mix.

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 12.0-cm; packing L1

Flow rate: 2 mL/min

Injection size: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between ethyl acrylate and methyl methacrylate

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each monomer in the portion of Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion taken:

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

r_U = peak response of each monomer from the *Sample solution*

r_S = peak response of each monomer from the *Standard solution*

C_S = concentration of each monomer in the *Standard solution* (µg/mL)

C_U = concentration of Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion in the *Sample stock solution* (mg/mL)

D = dilution factor for the preparation of the *Sample solution* from the *Sample stock solution*, 3

F = unit conversion factor, 10^{-3} mg/µg

Total impurities: NMT 0.01% of total monomers

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 1000 cfu/g, and the total yeasts and molds count does not exceed 100 cfu/g.

• **pH ⟨791⟩:** 5.5–8.6

• **Loss on Drying ⟨731⟩:** Dry a sample at 110° for 3 h: it loses between 68.5% and 71.5% of its weight.

• **Viscosity—Rotational Methods ⟨912⟩:** Equip a suitable rotational viscometer with an adapter comprising a cylindrical spindle rotating within an accurately machined chamber (or tube).[3] Mix the Dispersion, pipet the test specimen 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 shear rate under the test condition is NLT 1 s^{-1} and NMT 100 s^{-1}.[4] Measure the apparent viscosity, following the instrument manufacturer's directions.

Acceptance criteria: The viscosity is between 2 and 20 mPa · s.

• **Coagulum**

Sample: 100 g of Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion

Analysis: Weigh a stainless steel sieve having 125-µm openings or a suitable single-woven wire cloth with a mesh width of 125 µm, and filter the *Sample* through it. [Note—Suitable single-woven wire cloth mesh meets the requirements set in ISO 9044.]

Wash the sieve or the cloth with distilled water until a clear filtrate is obtained, and dry the sieve or the cloth to constant weight at 105°.

Acceptance criteria: The weight of the residue does not exceed 1000 mg (1%).

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store between 5° and 25°, with excursions permitted up to 30°. Do not freeze.

• **Labeling:** Label it to indicate the name and quantity of any added emulsifiers.

• **USP Reference Standards ⟨11⟩**

USP Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion RS

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[1] A simple glass microscope slide is suitable.

[2] KRS-5 consists of 42% thallium(I) bromide and 58% thallium(I) iodine by molecular weight. Suitable disks of silver chloride and of KRS-5 are available from www.photonic.saint-gobain.com, www.almazoptics.com, and www.internationalcrystal.net.

[3] 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.

[4] The cylindrical spindle rotates at 30 rpm.

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

Topic/Question	Contact	Expert Committee
ETHYL ACRYLATE AND METHYL METHACRYLATE COPOLYMER DISPERSION	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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