

Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion [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

- [Infrared Absorption](#) [〈 197 〉](#)

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:

$$\text{Result} = (rU/rS) \times (CS/CU) \times D \times F \times 100$$

rU = = peak response of each monomer from the Sample solution

rS = = peak response of each monomer from the Standard solution

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

CU = = concentration of each monomer 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 〈 911 〉](#): Equip a suitable rotational viscometer with an adapter comprising a cylindrical spindle rotating within an accurately machined chamber (or tube).