



Edition: BP 2025 (Ph. Eur. 11.6 update)

Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Dispersion 30 per cent



[General Notices](#)

(Ph. Eur. monograph 1129)

Action and use

Excipient.

Ph Eur

DEFINITION

Dispersion in water of a copolymer of methacrylic acid and ethyl acrylate having a mean relative molecular mass of about 250 000. The ratio of carboxylic groups to ester groups is about 1:1.

Content

46.0 per cent to 50.6 per cent of methacrylic acid units (residue on evaporation).

It may contain suitable surface-active agents such as sodium dodecyl sulfate and polysorbate 80.

CHARACTERS

Appearance

Opaque, white or almost white, slightly viscous liquid.

Solubility

Miscible with water. On addition of solvents such as acetone, anhydrous ethanol or 2-propanol, a precipitate is formed which dissolves on addition of excess solvent. It is miscible with a 40 g/L solution of sodium hydroxide.

IDENTIFICATION

A. Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [Ph. Eur. reference spectrum of methacrylic acid - ethyl acrylate copolymer \(1:1\) dispersion 30 per cent.](#)

B. It complies with the limits of the assay.

TESTS

[Viscosity \(2.2.10\)](#)

Maximum 15 mPa·s, determined using a rotating viscometer at 20 °C and at a shear rate of 50 s⁻¹.

Appearance of a film

Place 1 mL on a glass plate and allow to dry. A clear, brittle film is formed.

Particulate matter

Filter 100.0 g through a tared stainless steel sieve (90). Rinse with [water R](#) until a clear filtrate is obtained and dry at 100-105 °C. The residue weighs a maximum of 1.00 g.

Ethyl acrylate and methacrylic acid

Liquid chromatography ([2.2.29](#)).

Solution A Dissolve 3.5 g of [sodium perchlorate R](#) in [water for chromatography R](#) and dilute to 100.0 mL with the same solvent.

Blank solution Solution A, [methanol R1](#) (1:2 V/V).

Test solution Dissolve 10.0 g of the dispersion to be examined in [methanol R1](#) and dilute to 50.0 mL with the same solvent. To 5.0 mL of solution A add 10.0 mL of the solution dropwise whilst stirring continuously. Centrifuge until a clear supernatant is obtained. Use the clear supernatant as the test solution.

Reference solution Dissolve 50.0 mg of [ethyl acrylate R](#) and 50.0 mg of [methacrylic acid R](#) in 5 mL of [butanol R](#) and dilute to 50.0 mL with [methanol R1](#). Dilute 1.0 mL of the solution to 100.0 mL with [methanol R1](#). Dilute 2.0 mL of this solution to 10.0 mL with [methanol R1](#). Mix 10.0 mL of this solution and 5.0 mL of solution A.

Column:

— *size:* $l = 0.125$ m, $\varnothing = 4.6$ mm;

— *stationary phase:* [end-capped octadecylsilyl silica gel for chromatography R](#) (7 μ m).

Mobile phase Mix 20 volumes of [methanol R1](#) and 80 volumes of [water for chromatography R](#) previously adjusted to pH 2.0 with [phosphoric acid R](#).

Flow rate 2.0 mL/min.

Detection Spectrophotometer at 202 nm.

Injection 20 μ L.

Retention time Methacrylic acid = about 3 min, ethyl acrylate = about 8 min.

System suitability:

— **resolution**: minimum 5.0 between the peaks due to methacrylic acid and ethyl acrylate in the chromatogram obtained with the reference solution;

— the chromatogram obtained with the blank solution does not show peaks with the same retention times as ethyl acrylate or methacrylic acid.

Calculation of percentage contents:

— for ethyl acrylate and methacrylic acid, use the respective concentration of these substances in the reference solution.

Limit:

— **sum of the contents of ethyl acrylate and methacrylic acid**: maximum 0.01 per cent;

— **reporting threshold**: 1 ppm.

Residue on evaporation

28.5 per cent to 31.5 per cent.

Dry 1.000 g at 110 °C for 5 h. The residue weighs not less than 0.285 g and not more than 0.315 g.

Sulfated ash (2.4.14)

Maximum 0.2 per cent, determined on 1.0 g.

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (2.6.12).

TYMC: acceptance criterion 10^2 CFU/g (2.6.12).

ASSAY

Dissolve 1.500 g in a mixture of 40 mL of *water R* and 60 mL of *2-propanol R*. Titrate slowly while stirring with *0.5 M sodium hydroxide*, using *phenolphthalein solution R* as indicator.

1 mL of *0.5 M sodium hydroxide* is equivalent to 43.05 mg of $C_4H_6O_2$ (methacrylic acid units).

STORAGE

At a temperature of 5 °C to 25 °C, protected from freezing.

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product

during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristics may be relevant for methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 per cent used as a gastro-resistant coating agent.

Viscosity

(see Tests).

Appearance of a film

(see Tests).

Solubility of a film

Take a piece of the film obtained in the test for appearance of a film (see Tests), place it in a flask containing a 10.3 g/L solution of [hydrochloric acid R](#) and stir; it does not dissolve within 2 h. Take another piece of the film, place it in a flask containing [phosphate buffer solution pH 6.0 R](#) and stir; it dissolves within 1 h.

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