

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

**Limit:**

- *sum of the contents of ethyl acrylate and methacrylic acid*: maximum 0.1 per cent.

**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**

Protected from freezing. Handle the substance so as to minimise microbial contamination.

**LABELLING**

The label states, where applicable, the name and concentration of any surface-active agents.

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corrected 6.0

## METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1)

### Acidi methacrylici et methylis methacrylatis polymerisatum 1:1

**DEFINITION**

Copolymer of methacrylic acid and methyl methacrylate having a mean relative molecular mass of about 135 000. 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 (dried substance).

**CHARACTERS**

*Appearance*: white or almost white, free-flowing powder.

*Solubility*: practically insoluble in water, freely soluble in anhydrous ethanol and in 2-propanol, practically insoluble in ethyl acetate. It is freely soluble in a 40 g/L solution of sodium hydroxide.

**IDENTIFICATION**

A. Infrared absorption spectrophotometry (2.2.24).

*Comparison*: Ph. Eur. reference spectrum of *methacrylic acid - methyl methacrylate copolymer (1:1)*.

B. It complies with the limits of the assay.

**TESTS**

**Apparent viscosity** (2.2.10): 50 mPa·s to 200 mPa·s.

Dissolve a quantity of the substance to be examined corresponding to 37.5 g of the dried substance in a mixture of 7.9 g of *water R* and 254.6 g of *2-propanol R*. Determine the viscosity using a rotating viscometer at 20 °C and at a shear rate of  $10\text{ s}^{-1}$ .

**Appearance of a film**. Place 1 mL of the solution prepared in the test for apparent viscosity on a glass plate and allow to dry. A clear brittle film is formed.

**Methyl methacrylate and methacrylic acid**. Liquid chromatography (2.2.29).

*Blank solution*. To 50.0 mL of *methanol R* add 25.0 mL of the mobile phase.

*Test solution*. Dissolve 40 mg of the substance to be examined in 50.0 mL of *methanol R* and add 25.0 mL of the mobile phase.

*Reference solution*. Dissolve 10 mg of *methyl methacrylate R* and 10 mg of *methacrylic acid R* in *methanol R*, then dilute to 50.0 mL with the same solvent. Dilute 0.1 mL of this solution to 50.0 mL with *methanol R* and add 25.0 mL of the mobile phase.

**Column**:

- *size*:  $l = 0.10\text{ m}$ ,  $\varnothing = 4\text{ mm}$ ;
- *stationary phase*: octadecylsilyl silica gel for chromatography *R* (5  $\mu\text{m}$ ).

*Mobile phase*: *methanol R*, *phosphate buffer solution pH 2.0 R* (30:70 V/V).

*Flow rate*: 2.5 mL/min.

*Detection*: spectrophotometer at 202 nm.

*Injection*: 50  $\mu\text{L}$ .

**System suitability**:

- *resolution*: minimum 2.0 between the peaks due to methyl methacrylate and methacrylic acid 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 methyl methacrylate or methacrylic acid.

**Limit**:

- *sum of the contents of methyl methacrylate and methacrylic acid*: maximum 0.1 per cent.

**Loss on drying** (2.2.32): maximum 5.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 6 h.

**Sulfated ash** (2.4.14): maximum 0.1 per cent, determined on 1.0 g.

**ASSAY**

Dissolve 1.000 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).

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corrected 6.0

## METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2)

### Acidi methacrylici et methylis methacrylatis polymerisatum 1:2

**DEFINITION**

Copolymer of methacrylic acid and methyl methacrylate having a mean relative molecular mass of about 135 000. The ratio of carboxylic groups to ester groups is about 1:2.

*Content*: 27.6 per cent to 30.7 per cent of methacrylic acid units (dried substance).

**CHARACTERS**

*Appearance*: white or almost white, free-flowing powder.

*Solubility*: practically insoluble in water, freely soluble in anhydrous ethanol and in 2-propanol, practically insoluble in ethyl acetate. It is freely soluble in a 40 g/L solution of sodium hydroxide.

**IDENTIFICATION**

A. Infrared absorption spectrophotometry (2.2.24).

*Comparison*: Ph. Eur. reference spectrum of *methacrylic acid - methyl methacrylate copolymer (1:2)*.