Methacrylic acid - methyl methacrylate copolymer (1:1)

DEFINITION
Methacrylic acid - methyl methacrylate copolymer (1:1) is a 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. It contains not less than 46.0 per cent m/m and not more than 50.6 per cent of methacrylic acid units, calculated with reference to the dried substance.

CHARACTERS
A white, free-flowing powder, practically insoluble in water, freely soluble in 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. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the Ph. Eur. reference spectrum of methacrylic acid - methyl methacrylate copolymer (1:1).

B. It complies with the limits of the assay.

TESTS
Apparent viscosity. 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 (2.2.10) using a rotating viscometer at 20 °C. At a shear rate of 10 s⁻¹, the apparent viscosity is not less than 50 mPAs and not more than 200 mPAs.

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

Methyl methacrylate and methacrylic acid. Total content: not more than 0.1 per cent, determined by liquid chromatography (2.2.29).

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 C₅H₈O₂ (methacrylic acid units).

STORAGE
Store 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.
is not valid if the chromatogram obtained with the blank solution shows peaks with the same retention times as methyl methacrylate or methacrylic acid.

Calculate the percentage content of monomers from the area of the peaks in the chromatograms obtained with the test solution and the reference solution and from the content of monomers in the reference solution.

**Loss on drying** (2.2.32). Not more than 5.0 per cent, determined on 1.000 g by drying at 100 °C to 105 °C for 6 h.

**Sulphated ash** (2.4.14). Not more than 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 C₄H₆O₂ (methacrylic acid units).

**01/2005:1130**

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

Acidum methacrylicum et methylis methacrylas polymerisatum 1:2

**DEFINITION**

Methacrylic acid - methyl methacrylate copolymer (1:2) is a 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. It contains not less than 27.6 per cent m/m and not more than 30.7 per cent m/m of methacrylic acid units, calculated with reference to the dried substance.

**CHARACTERS**

A white, free-flowing powder, practically insoluble in water, freely soluble in 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. Examine by infrared absorption spectrophotometry (2.2.24), comparing with the Ph. Eur. reference spectrum of methacrylic acid - methyl methacrylate copolymer (1:2).

B. It complies with the limits of the assay.

**TESTS**

**Apparent viscosity.** Dissolve a quantity of 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 (2.2.10) using a rotating viscometer at 20 °C. At a shear rate of 10 s⁻¹, the apparent viscosity is not less than 50 mPas and not more than 200 mPas.

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

**Methyl methacrylate and methacrylic acid.** Total content: not more than 0.1 per cent, determined by liquid chromatography (2.2.29).

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

**Reference solution.** Dissolve 10 mg each of methyl methacrylate R and methacrylic acid R in methanol R and 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 mobile phase.

The chromatographic procedure may be carried out using:

- a stainless steel column 0.10 m long and 4 mm in internal diameter packed with octadecysilyl silica gel for chromatography R (5 µm),

- as mobile phase at a flow rate of 2.5 ml/min a mixture of 30 volumes of methanol R and 70 volumes of phosphate buffer solution pH 2.0 R,

- as detector a spectrophotometer set at 202 nm.

Inject 50 µl of each solution. The test is not valid unless the resolution between the peaks corresponding to methyl methacrylate and methacrylic acid in the chromatogram obtained with the reference solution is at least 2.0. The test is not valid if the chromatogram obtained with the blank solution shows peaks with the same retention times as methyl methacrylate or methacrylic acid.

Calculate the percentage content of monomers from the area of the peaks in the chromatograms obtained with the test solution and the reference solution and from the content of monomers in the reference solution.

**Loss on drying** (2.2.32). Not more than 5.0 per cent, determined on 1.000 g by drying in an oven at 100 °C to 105 °C for 6 h.

**Sulphated ash** (2.4.14). Not more than 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 C₄H₆O₂ (methacrylic acid units).

**01/2005:0408**

**METHADONE HYDROCHLORIDE**

Methadoni hydrochloridum

![Methadone hydrochloride structure](image)

C₂₃H₃₃CINO

M, 345.9

**DEFINITION**

Methadone hydrochloride contains not less than 99.0 per cent and not more than the equivalent of 101.0 per cent of (6RS)-6-(dimethylamino)-4,4-diphenylheptan-3-one hydrochloride, calculated with reference to the dried substance.

**CHARACTERS**

A white, crystalline powder, soluble in water, freely soluble in alcohol.