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 not more than 1.00 g.

Ethyl acrylate 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 dispersion 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 *ethyl acrylate 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 m, Ø = 4 mm;
- *stationary phase*: *octadecylsilyl silica gel for chromatography R* (5 µm).

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 µl.

System suitability:

- *resolution*: minimum 2.0 between the peaks due to ethyl acrylate 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 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.

Sulphated ash (*2.4.14*): maximum 0.2 per cent, determined on 1.0 g.

Microbial contamination. Total viable aerobic count (*2.6.12*) not more than 10^3 micro-organisms per gram, determined by plate count.

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.

01/2008:1127
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 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 m, Ø = 4 mm;
- *stationary phase*: *octadecylsilyl silica gel for chromatography R* (5 µm).

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 µl.

Monographs M

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.

Sulphated 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).

01/2008:1130
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)*.

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 s^{-1}.

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. 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 m, Ø = 4 mm;
- *stationary phase*: *octadecylsilyl silica gel for chromatography R* (5 µm).

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 µl.

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.

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

ASSAY

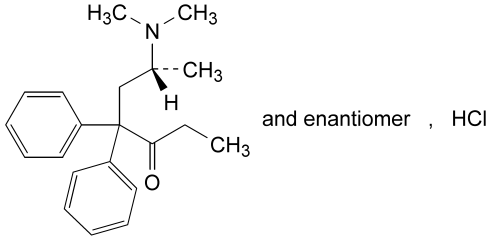
Dissolve 1.000 g in a mixture of 40 ml of *water R* and 60 ml of *2-propanol R*. Titrate slowly while stirring with *0.5 M sodium hydroxide*, using *phenolphthalein solution R* as indicator.

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

01/2008:0408
corrected 6.0

METHADONE HYDROCHLORIDE

Methadoni hydrochloridum



$C_{21}H_{28}ClNO$ M_r 345.9
[1095-90-5]

Monographs M