Particulate matter. Filter 100.0 g through a tared stainless steel sieve (90). Rinse with water 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).


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 10³ 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 CH₂(CO₂H)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.

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).


Flow rate: 2.5 ml/min.

Detection: spectrophotometer at 202 nm.

Injection: 50 µl.
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 anhydrous ethanol and in 2-propanol, practically insoluble in water, freely soluble in

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.

METHADONE HYDROCHLORIDE

Methadoni hydrochloridum

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: 1 = 0.10 m, Ø = 4 mm;
- stationary phase: octadecylsilyl silica gel for chromatography (5 µm).
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.

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).

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

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.

01/2008:1130 corrected 6.0

01/2008:0408 corrected 6.0