Technical Information

EUDRAGIT® E 100, EUDRAGIT® E PO and EUDRAGIT® E 12,5

Specification and Test Methods

Ph. Eur.	Basic Butylated Methacrylate Copolymer
USP/NF	Amino Methacrylate Copolymer - NF
JPE	Aminoalkyl Methacrylate Copolymer E

1 Commercial form

EUDRAGIT® E 100

Solid substance

EUDRAGIT® E 100 is described in the monographs quoted above.

EUDRAGIT® E PO

Solid substance obtained from EUDRAGIT® E 100.

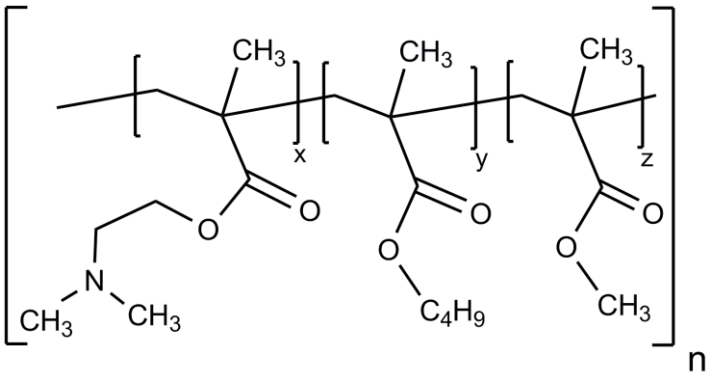
EUDRAGIT® E PO is described in the Ph. Eur. and JPE monographs quoted above.
The polymer conforms to the USP/NF monograph quoted above.

EUDRAGIT® E 12,5

Solution of EUDRAGIT® E 100 with 12.5 % (w/w) dry substance in a mixture of 60 % (w/w) Isopropyl Alcohol Ph. Eur. / USP and 40 % (w/w) Acetone Ph. Eur. / NF.

2 Chemical structure

EUDRAGIT® E 100 is a cationic copolymer based on dimethylaminoethyl methacrylate, butyl methacrylate, and methyl methacrylate with a ratio of 2:1:1.



The monomers are randomly distributed along the copolymer chain. Based on SEC method the weight average molar mass (Mw) of EUDRAGIT® E 100; EUDRAGIT® E PO and EUDRAGIT® E 12,5 is approximately 47,000 g/mol.

3 Characters

Description

EUDRAGIT® E 100: colourless to yellow tinged granules with a characteristic amine-like odour.
EUDRAGIT® E PO: white powder with a characteristic amine-like odour.
EUDRAGIT® E 12,5: light yellow liquid of low viscosity, clear to slightly cloudy with a characteristic odour of the solvents.

Solubility

1 g of EUDRAGIT® E 100 or EUDRAGIT® E PO dissolves in 7 g methanol, ethanol, isopropyl alcohol, acetone, ethyl acetate, methylene chloride or 1 N hydrochloric acid to give clear to slightly cloudy solutions. EUDRAGIT® E 12,5 is mixable with these solvents and with petroleum ether in a ratio of 1:1.

The solid substance is practically insoluble in petroleum ether and water. The polymer is precipitated from EUDRAGIT® E 12,5 when mixed with water in a ratio of 1:1.

4 Tests

Test solution

Either EUDRAGIT® E 12,5 is used for the Test solution, or a corresponding solution of EUDRAGIT® E 100 or EUDRAGIT® E PO: 12.5 % (w/w) dry substance is dissolved in a mixture of 60 % (w/w) isopropyl alcohol and 40 % (w/w) acetone.

Particle size

EUDRAGIT® E PO: Dv50 < 50 µm
The particle size is determined by laser light diffraction according to Ph. Eur. 2.9.31 / light diffraction measurement USP <429>.

Film formation

When the Test solution is poured onto a glass plate, a clear film forms upon evaporation of the solvents.

Dry substance / Residue on evaporation

EUDRAGIT® E 100 / EUDRAGIT® E PO: not less than 98.0 %
The test is performed according to Ph. Eur. 2.2.32 d.
1 g is dried in an oven for 3 hrs at 110°C.

EUDRAGIT® E 12,5: 11.9 - 13.1 %
The test is performed according to Ph. Eur. 2.2.32 d. 20 g quartz sand are mixed with 1 g of the solution and dried in an oven for 5 hrs at 110°C.

Loss on drying

EUDRAGIT® E 100 / EUDRAGIT® E PO: max. 2.0 % according to "Dry substance / Residue on evaporation".

Assay

Dimethylaminoethyl (DMAE) groups on dry substance (DS): 20.8 - 25.5 %
Alkali value: 162 – 198 mg KOH per g DS

The assay is performed according to Ph. Eur. 2.2.20 "Potentiometric titration" or USP <541>. 0.2 g EUDRAGIT® E 100 / EUDRAGIT® E PO or 1.6 g EUDRAGIT® E 12,5 are dissolved in 96 ml glacial acetic acid and 4 ml water. 0.1 N perchloric acid is used as the titrant. 1 mL of 0.1 N perchloric acid is equivalent to 7.21 mg of dimethylaminoethyl groups.

The alkali value (AV) states how many mg KOH are equivalent to the basic groups contained in 1 g dry substance (DS).

$$\text{AV (mg KOH / g DS)} = \frac{\text{ml 0.1 N } HClO_4 \cdot 561}{\text{sample weight (g)} \cdot \text{DS (\%)}}$$

DMAE groups (%) = AV (mg KOH / g DS) · 0.1286

JPE: EUDRAGIT® E 100 / EUDRAGIT® E PO: 4.0 - 6.0 % Nitrogen on dry substance
The test is performed according to JP method “Nitrogen determination”.

Colour

Absorbance (A): max. 0.300
The test is performed according to Ph. Eur. 2.2.25 or USP monograph.
The yellow colour of the test solution is determined against water at 420 nm in a 1 cm cuvette.

Viscosity / Apparent viscosity

3 - 6 mPa · s
The viscosity of the Test solution is determined by means of a Brookfield viscometer (UL adapter / 30 rpm / 20°C).
The test is performed according to Ph. Eur. 2.2.10 or USP <912> method II.

Viscosity / Kinematic viscosity

JPE: EUDRAGIT® E 100 / EUDRAGIT® E PO: 2.5 - 5.5 mm^2 / s
The test is performed according to the JPE monograph.

Refractive index

n_D^{20}: 1.380 - 1.385
The refractive index of the Test solution is determined according to Ph. Eur. 2.2.6.

Relative density

d_{20}^{20}: 0.811 - 0.821
The relative density of the Test solution is determined according to Ph. Eur. 2.2.5.

5 Purity

Sulphated ash / Residue on ignition

Max. 0.1 %
The test is performed according to Ph. Eur. 2.4.14 or USP <281>.
1 g EUDRAGIT® E 100, EUDRAGIT® E PO or EUDRAGIT® E 12,5 is used for the test.

Heavy metals

Max. 20 ppm
The test is performed according to Ph. Eur. 2.4.8 method C or USP <231> method II.
1 g EUDRAGIT® E 100, EUDRAGIT® E PO or EUDRAGIT® E 12,5 is used for the test.

Arsenic

JPE: EUDRAGIT® E 100 / EUDRAGIT® E PO: max. 2 ppm
The test is performed according to JP Method 3.
1.0 g EUDRAGIT® E 100 or EUDRAGIT® E PO is used for the test.

Monomers

EUDRAGIT® E 100 / EUDRAGIT® E PO total of monomers: < 2500 ppm
Butyl methacrylate: < 1000 ppm
Methyl methacrylate: < 500 ppm
Dimethylaminoethyl methacrylate: < 1000 ppm

EUDRAGIT® E 12,5: total of monomers max. 0.04 %

The test is performed according to the Ph. Eur., USP/NF or JPE monograph on 1 g EUDRAGIT® E 100 / EUDRAGIT® E PO or 8 g EUDRAGIT® E 12,5.

Residual Solvents

EUDRAGIT® E 100 / EUDRAGIT® E PO:
Contains small amounts of 2-Propanol with concentration below 0.5 %.
Small amounts of Methanol may be detectable in the product within the minimum stability period. The concentration remains below 0.1 %.
Small amounts of n-Butanol may be detectable in the product within the minimum stability period. The concentration remains below 0.5 %.
The test is performed according to Ph. Eur. 2.4.24 sample preparation 2 or USP <467> for water-insoluble substances.

EUDRAGIT® E 12,5:
The product is a solution of polymer in 2-Propanol and Acetone.

Microbial count

Total aerobic microbial count (TAMC): max. 10^3 CFU / g
Total combined yeasts and moulds count (TYMC): max. 10^2 CFU / g
(Acceptance criteria according to Ph. Eur. 5.1.4 / USP <1111>)
The test is performed according to Ph. Eur. 2.6.12 or USP <61>.

6 Identity testing

First identification

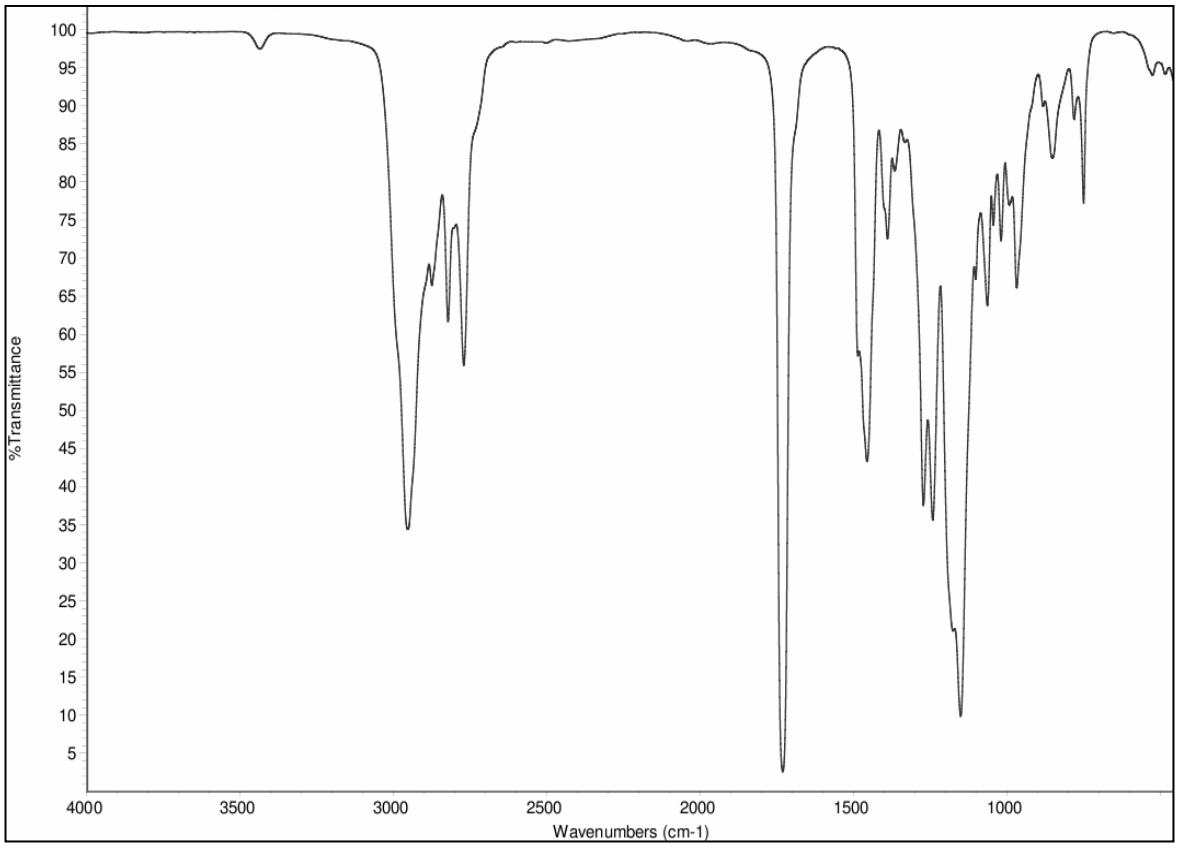
The material must comply with the tests for "Assay" and "Viscosity / Apparent viscosity."

Second identification

IR spectroscopy on a dry film approx. 15 µm thick. To obtain the film, a few drops of the Test solution are placed on a crystal disc (KBr, NaCl) and dried in vacuo for about 2 hours at 70°C.

The figure on page 5 shows the characteristic bands of the ester groups at 1,150 - 1,190, 1,240 and 1,270 cm^{-1}, as well as the C = O ester vibration at 1,730 cm^{-1}. In addition, CH_X vibrations can be discerned at 1,385, 1,450 - 1,490 and 2,950 cm^{-1}. The absorptions at 2,770 and 2,820 cm^{-1} can be assigned to the dimethylamino groups.

EUDRAGIT® E 100 / EUDRAGIT® E PO / EUDRAGIT® E 12,5



7 Detection in dosage forms

The dosage forms are extracted using the solvents listed under “Solubility,” if necessary after crushing. Insoluble substances are isolated by filtration or centrifugation. The clear filtrate is boiled down and the residue identified by IR spectroscopy.

8 Storage

EUDRAGIT® E 100: Protect from warm temperatures (USP, General Notices). Protect from moisture. Any storage between 8°C and 25°C fulfils this requirement. EUDRAGIT® E 100 tends to form lumps at warm temperatures (≥ 30°C). This has no influence on the quality. The lumps are easily broken up again.

EUDRAGIT® E PO: Store at temperatures up to 25°C. Protect from moisture. Any storage between 8°C and 25°C fulfils this requirement. Temperatures above 25°C will cause caking of EUDRAGIT® E PO.

EUDRAGIT® E 12,5: Protect from warm temperatures (USP, General Notices). Store in tightly closed containers.

9 Stability

Minimum stability dates are given on the product labels and batch-related Certificates of Analysis. Storage Stability data are available upon request.

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