

**EUDRAGIT® L 30 D-55**

## Specification and Test Methods

<b>Ph. Eur.</b>	Methacrylic Acid - Ethyl Acrylate Copolymer (1:1) Dispersion 30 Per Cent
<b>USP/NF</b>	Methacrylic Acid Copolymer Dispersion - NF * Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion – NF ** * Current monograph name valid until May 1, 2017 ** New monograph name valid as of May 1, 2012, mandatory as of May 1, 2017
<b>JPE</b>	Methacrylic Acid Copolymer LD

**1 Commercial form**

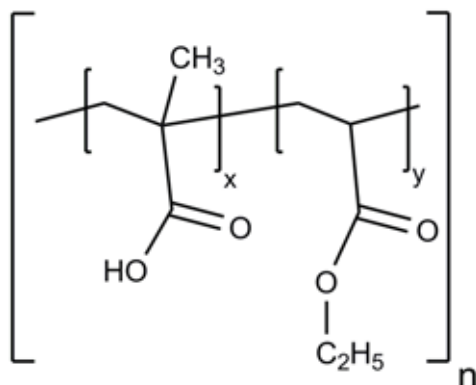
Aqueous dispersion with 30% dry substance. The water is tested according to the specifications of "Purified Water in bulk" Ph. Eur. and according to the specifications for Conductivity of "Purified Water" USP.

The dispersion contains 0.7% Sodium Laurilsulfate Ph. Eur. / NF and 2.3% Polysorbate 80 Ph. Eur. / NF on solid substance, as emulsifiers.

EUDRAGIT® L 30 D-55 is described in the monographs quoted above.

**2 Chemical structure**

EUDRAGIT® L 30 D-55 is the aqueous dispersion of an anionic copolymer based on methacrylic acid and ethyl acrylate. The ratio of the free carboxyl groups to the ester groups is approx. 1:1.



The monomers are randomly distributed along the copolymer chain. Based on SEC method the weight average molar mass ( $M_w$ ) of EUDRAGIT® L 30 D-55 is approx. 320,000 g/mol.

### 3 Characters

#### Description

Milky-white liquid of low viscosity with a faint characteristic odour.

#### Solubility

The dispersion is miscible with water in any proportion, the milky-white appearance being retained. A clear or slightly cloudy, viscous solution is obtained by mixing 1 part EUDRAGIT® L 30 D-55 with 5 parts acetone. The same results are obtained by mixing with ethanol or isopropyl alcohol; initially, the polymer is precipitated, but then dissolves again in the excess organic solvent.

A clear or slightly cloudy liquid is obtained by mixing 1 part EUDRAGIT® L 30 D-55 with 2 parts 1 N sodium hydroxide.

### 4 Tests

#### Film formation

10 g EUDRAGIT® L 30 D-55 are mixed with 0.3 g triethyl citrate. When the dispersion is poured onto a glass plate, a clear film forms upon evaporation of the water.

#### Dry substance / Residue on evaporation

28.5 - 31.5 %

The test is performed according to Ph. Eur. 2.2.32 method d. 1 g of the dispersion is dried in an oven for 5 hrs at 110 °C. The dispersion must form a clear film after drying.

#### Loss on drying

68.5 - 71.5 % according to "Dry substance / Residue on evaporation".

#### Assay

46.0 - 50.6 % methacrylic acid units on dry substance (DS)

Acid value: 300 - 330 mg KOH per g DS

The assay is performed according to Ph. Eur. 2.2.20 "Potentiometric titration" or USP <541>. Approx. 1.5 g EUDRAGIT® L 30 D-55 is dissolved in 60 ml isopropyl alcohol and 40 ml water while stirring for about 15 minutes. Sodium hydroxide (NaOH) 0.5 N is used as the titrant. 1 ml 0.5 N NaOH corresponds to 43.045 mg methacrylic acid units.

$$\text{Methacrylic acid units (\% on DS)} = \frac{\text{ml 0.5 N NaOH} \cdot 430.45}{\text{sample weight (g)} \cdot \text{DS (\%)}}$$

*The acid value (AV) states how many mg KOH are required to neutralise the acid groups contained in 1 g dry substance.*

$$\text{AV (mg KOH / g DS)} = \text{methacrylic acid units (\%)} \cdot 6.517$$

JPE: 11.5 – 15.5 % methacrylic acid units on the dispersion as supplied according to the JPE monograph.

### **Viscosity / Apparent viscosity**

3 - 10 mPa · s

The viscosity of the dispersion 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: 3 - 15 mm<sup>2</sup> / s

The test is performed according to the JPE monograph.

### **pH**

2.1 - 3.0

The pH is determined according to Ph. Eur. 2.2.3 or USP <791>.

### **Relative density**

$d_{20}^{20}$ : 1.062 - 1.072

The relative density is determined according to Ph. Eur. 2.2.5.

### **Coagulum content**

Max. 1,000 mg / 100 g

A stainless steel wire cloth with a mesh size of 0.09 mm (mesh number 90, ISO) is accurately weighed. 100 g EUDRAGIT® L 30 D-55 are filtered through this cloth, which is then washed with water until a clear filtrate is obtained, dried to constant weight at 105 °C and weighed to determine the filtration residue.

## 5 Purity

### Sulphated ash / Residue on ignition

Max. 0.12 %

The test is performed according to Ph. Eur. 2.4.14 or USP <281>. 1 g EUDRAGIT® L 30 D-55 is used for the test.

JPE: Max. 0.10 %

The test is performed according to the JP method. 2 g of EUDRAGIT® L 30 D-55 are 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® L 30 D-55 is used for the test.

JPE: Max. 10 ppm

The test is performed according to the JPE monograph. 2.0 g EUDRAGIT® L 30 D-55 are used for the test.

### Arsenic

JPE: Max. 1 ppm

The test is performed according to JP method 3. 2.0 g EUDRAGIT® L 30 D-55 are used for the test.

### Monomers

Total of Monomers: Max. 100 ppm

Methacrylic acid: Max. 50 ppm

Ethyl acrylate: Max. 50 ppm

The test is performed according to the Ph. Eur., USP/NF or JPE monograph.

### Residual Solvents

Organic solvents are not used in the manufacture, packing and storage of this product. Small amounts of Ethanol 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.

### 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

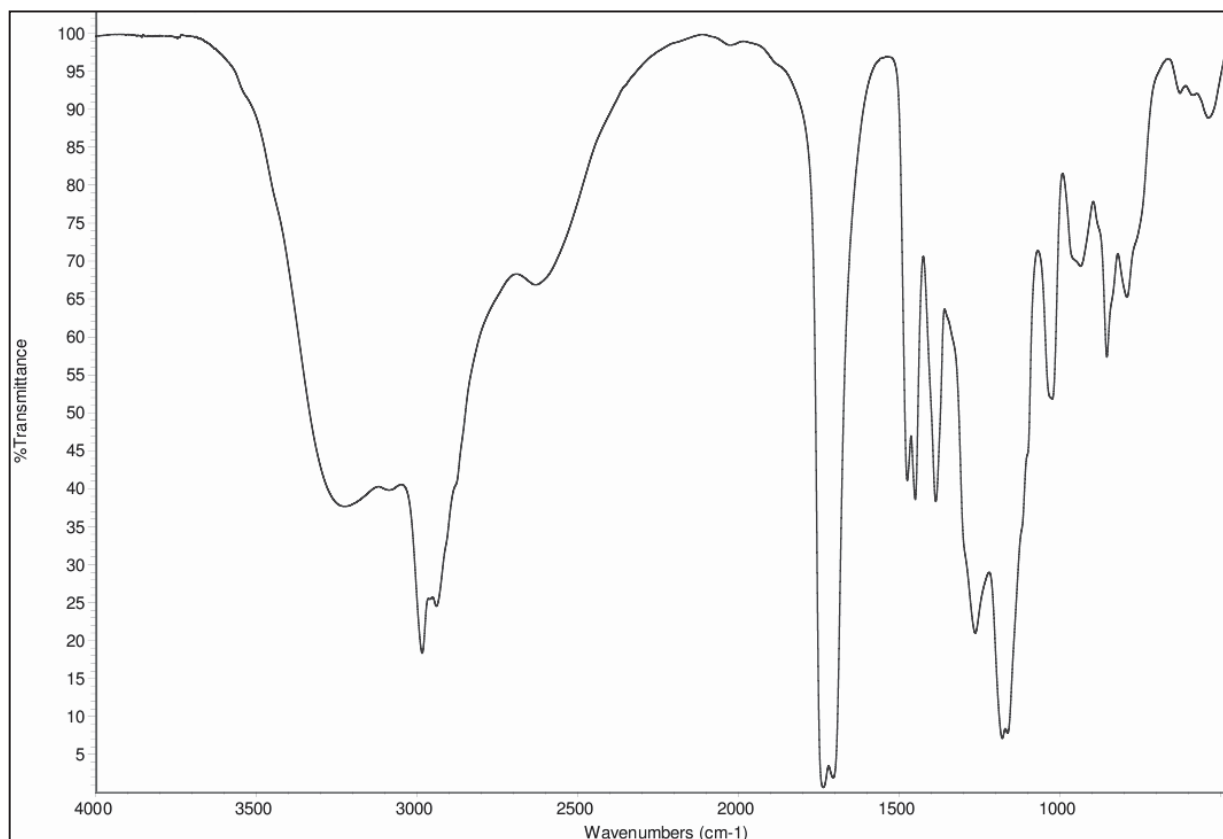
The material must comply with the tests for "Assay" and "Viscosity / Apparent viscosity."

### Second identification

IR spectroscopy on a dry film approx. 15  $\mu\text{m}$  thick. The film is obtained by applying one drop of EUDRAGIT<sup>®</sup> L 30 D-55 to a glass plate and covering with a water-resistant crystal disc (AgCl, KRS 5). By lightly pressing on and then removing the crystal disc, a clear film is obtained after a drying period of about 15 minutes at 80 °C.

The figure on page 5 shows the characteristic bands of the C = O vibrations of the carboxylic acid groups at 1,705  $\text{cm}^{-1}$  and of the esterified carboxylic groups at 1,735  $\text{cm}^{-1}$ , further ester vibrations at 1,150 - 1,180 and 1,250 - 1,270  $\text{cm}^{-1}$ , strongly associated OH vibrations in the range 2,500 - 3,500  $\text{cm}^{-1}$  as well as  $\text{CH}_x$  vibrations at 1,385, 1,450, 1,475 and 2,940 - 2,990  $\text{cm}^{-1}$ .

### EUDRAGIT<sup>®</sup> L 30 D-55



## 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 and handling

Store at controlled room temperature (USP, General Notices). Protect from freezing. Any storage between 8 °C and 25 °C fulfils this requirement.

Avoid contamination during sampling. Containers that have been opened for use should be closed again immediately and the content used up within the next few weeks.

## 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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® = registered trademark  
EUDRAGIT = reg. trademark of Evonik Röhm GmbH, Darmstadt, Germany

May 2014

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## EUDRAGIT® L 30 D-55

### Enteric coating with talc as anti-tacking agent

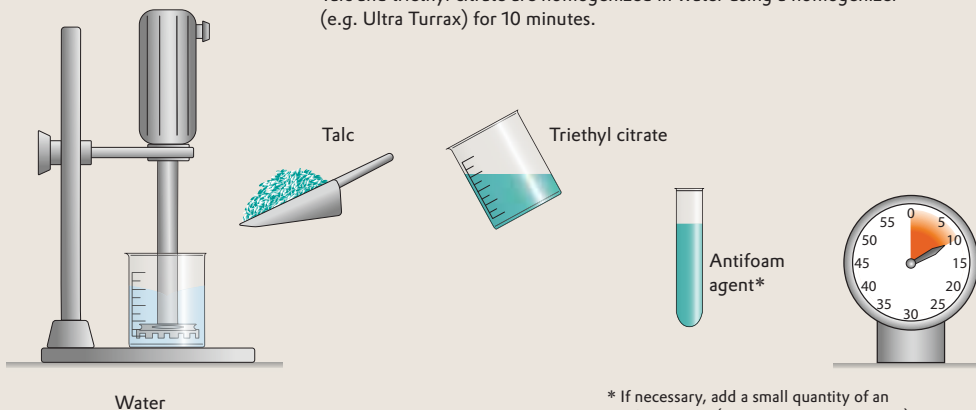
#### Formulation

The following formulation is calculated for a standard quantity of 1 kg spray suspension. The quantity for film coating of your substrate depends on the application and surface area of the substrate. Please contact us if you need assistance to calculate your individual formulation.

Function	Ingredient	Quantity based on dry polymer [%]	Quantity to be weighed [g]	Dry substance [g]
Polymer	EUDRAGIT® L 30 D-55		416.7	125.0
Plasticizer	Triethyl citrate	10.0	12.5	12.5
Anti-tacking	Talc	50.0	62.5	62.5
Diluent	Water		508.3	
<b>Total</b>			<b>1000.0</b>	<b>200.0</b>

#### Excipient suspension

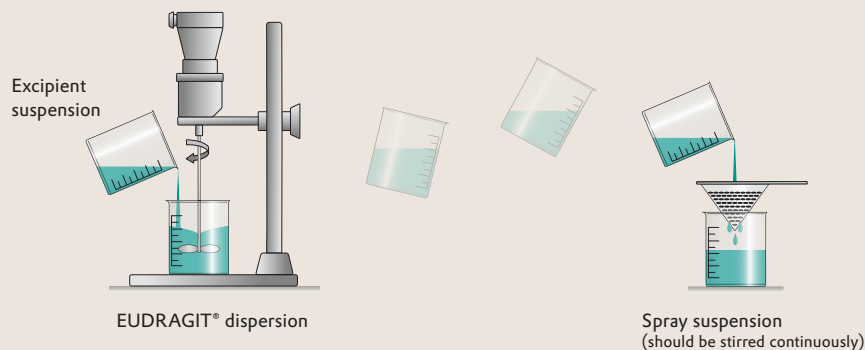
Talc and triethyl citrate are homogenized in water using a homogenizer (e.g. Ultra Turrax) for 10 minutes.



#### Spray suspension

Pour the excipient suspension slowly into the EUDRAGIT® dispersion while stirring gently with a conventional stirrer.

Pass the spray suspension through a 0.5 mm sieve.



## Coating parameters:

The tables below give examples of process parameters for film coating. Please do not hesitate to contact us if you need assistance to find the right parameters for your specific equipment, batch size, and substrate combination.

### EUDRAGIT® L 30 D-55 on particles (1 kg) in Glatt GPCG 1.1, top spray

Equipment setup		
Nozzle bore	mm	1.2
Distance nozzle/product	cm	10
Internal silicone tube diameter	mm	2
Process parameter setup		
Atomizing air pressure	bar	1.8
Filter rattling time	s	5
Filter rattling interval	s	30
Drying air volume	m <sup>3</sup> /h	60–90
Drying air capacity	m <sup>3</sup> /min/kg	1.0–1.5
Process data		
Inlet air temperature	°C	35–45
Exhaust air temperature	°C	26–29
Product temperature	°C	25–28
Spray rate	g/min/kg	10–15
Final drying at 40 °C (circulating air oven)	h	2

### EUDRAGIT® L 30 D-55 on tablets (2.5 kg) in O'Hara LabCoat

Equipment setup		
Drum speed	rpm	20
No. of spray guns		1
Nozzle bore	mm	1.2
Distance tablet bed/spray gun	cm	10
Internal tube diameter	mm	2
Process parameter setup		
Atomizing air pressure	bar	1.1
Flat pattern pressure	bar	1.1
Drying air volume	m <sup>3</sup> /h	150–200
Drying air capacity	m <sup>3</sup> /min/kg	1.0–1.3
Exhaust air volume	m <sup>3</sup> /h	>150–200
Process data		
Inlet air temperature	°C	45–60
Exhaust air temperature	°C	35–40
Product temperature	°C	30–33
Pan diff. pressure	mbar	–0.5
Spray rate	g/min/kg	3–6
Final drying at 40 °C (circulating air oven)	h	2

\* = registered trademark EUDRAGIT is a registered trademark of Evonik Röhm GmbH, Darmstadt, Germany.

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