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Röhm Pharma Polymers

Enteric coatings with EUDRAGIT â L/S from aqueous dispersions. Tablets coated with EUDRAGIT® L 30 D-55

Spraying process for the manufacture of taste- and odour-masking, clear-transparent enteric sealing coats with EUDRAGIT® L 30 D-55 finished in a pan coating unit.

Operating method

The coating suspension is sprayed onto the rotating cores, which are prewarmed to about 30 °C, by means of an air spray gun. Spray rate, inlet air quantity and inlet air temperature are adjusted in such a way that spraying can be performed continuously. During the process, the tablets should be maintained at a temperature of approx. 25 to 35 °C.
Twinning, i.e. sticking together of tablets, can be avoided by adding suitable glidants (talc, magnesium stearate, kaolin) to the EUDRAGIT® L 30 D-55 spray suspension.

If twinning does occur, spraying must be interrupted until the tablets are dry and once more able to tumble freely. Subsequently, processing may be continued at a reduced spray rate.

The following polymers, dissolved in organic solvents, are recommended for subcoating of extremely water-sensitive active ingredients:

EUDRAGIT® E 12,5, EUDRAGIT® E 100 ; EUDRAGIT® RL/RS 12,5 ;
EUDRAGIT® RL/RS 100 ; EUDRAGIT® L/S 12,5 ; EUDRAGIT® L/S 100 ;
EUDRAGIT® L 100-55

Similarly to colloidal systems, aqueous dispersions are adversely affected by various factors. Coagulation may occur in the presence of electrolytes, organic solvents or finely dispersed pigments, due to changes in pH, foam formation, heat or frost, or high shear in high-speed mixers and mills.

Finely dispersed pigments in polymer dispersions may cause speckling. Added emulsifiers (polysorbate, polyethylene glycol, polyvinyl pyrrolidone, Na carboxymethylcellulose, etc.) have a stabilizing effect. When speckling leads to coagulation, these dispersions cannot be redispersed and must be discarded.
EUDRAGIT® L 30 D-55 dispersions are incompatible with magnesium stearate (thickening or coagulation), but magnesium stearate contained in tablets affects neither the spray suspension nor the film properties.

Typical formulation

The following formulation gives the polymer and excipient quantities required for coating 3 kg of medium-sized tablets (diameter 8 mm, weight 200 mg) at a polymer weight of 5.7 mg/cm².

First, a 10% solution is prepared from polyethylene glycol 6000 and part of the water, which is then added to the rest of the water together with talc and antifoam (silicone) emulsion. This suspension is homogenized in suitable equipment (Ultra-Turrax, geared colloid mill, ball mill) and finally stirred into the EUDRAGIT® L 30 D-55 dispersion just before use. After filtration through a 0.1mm sieve, the suspension should be gently stirred throughout the spraying operation.

Typical formulation

Enteric film coating with EUDRAGIT® L 30 D-55

	Parts by weight
EUDRAGIT® L 30 D-55	533 g
Polyethylene glycol 6000*	16 g
Talc	16 g
Antifoam emulsion	1 g
Water	434 g
	å **1,000 g**
Solids content of the spray suspension:	19.3%
Content in dry polymer substance:	16.0%

* added as a 33% pigment suspension in part of the water before dispersing

This gives a polymer (160 g from 533 g EUDRAGIT® L 30 -55) weight of L = 7.5 mg/cm² by a tablets surface of S = 188.5 mm².

EUDRAGIT L 30 D-55 can also be obtained by redispersing the solid EUDRAGIT® L 100-55 in water.

Operating data
Example **EUDRAGIT® L 30 D-55**

Technical data

Coating unit	stainless steel coating pan, ∅ 350 mm, angle of inclination 35°
Feed pump	peristaltic pump with silicone tube, internal ∅ 3 mm
Spray system	Walther Bingo air spray gun, nozzle ∅ 10 mm (round spray)
Distance nozzle/tablets	100 mm

Coating data

Tablets	analgetic, engraved an both sides, ∅ 8 mm, 3.5 mm in height, 200 g in weight; hardness 70 N, disintegration in demin. water: 5 min, friability < 0.1% (100 rev within 4 min)
Batch size	3 kg
Spray suspension	750 g, corresponding to 145 g solids or 4.8 wt.-% an tablet quantity, 120 g polymer equivalent to 4 wt.-% an tablet quantity, ratio 5:1 to other excipients

Process data	**Preheating**	**Spraying**	**Drying**
Duration	3 min	75 min	10 min
Inlet air quantity	1 m^3/min	1 m^3/min	1 m^3/min
Inlet air temperature	50 °C	50 °C	50 °C
Tablet temperature	30 °C	30 °C	40 °C
Pan speed	10 rpm	40 rpm	10 rpm
Atomizing air pressure		0.5 bar	
Spray rate	-	10 g/min	-
Pump speed		4 rpm	

Other process data

Spray rate	3.33 g suspension/min/kg product 0.64 g solids/min/kg product
Evaporation rate	2.69 g/min/kg product
Polymer quantity	4.25 mg/cm^2
Spraying process	continuous
Total process time	88 min
Post-drying	6 hours in drying cabinet at 40 °C

Results

Appearance	uniform, smooth and glossy coating with engravings well preserved
Gastroresistance	for 2 hours (BP, pH 1.0), then disintegration in intestinal fluid (BP, pH 6.8) within max 8 min, no loss of enteric property after friability test
Attrition	0%
Hardness	125 N
Recommendations	see our Process Technology Sheets for scale-up instructions