

Enteric coatings from organic solutions. Tablets, coloured with EUDRAGIT[®] L/S.

Spraying process for the manufacture of taste- and odour-masking, colourless and transparent enteric sealing coats with EUDRAGIT[®] L 12.5 on tablets 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 12.5 spray suspension.

If twinning does occur, spray application 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 formulation gives the polymer and excipient quantities required for coating 10 kg of medium-sized tablets (8 mm in diameter, 200 mg in weight) at a polymer weight of 2.5 mg/cm².

For preparation of the pigmented top coat suspension, the solvent mixture acetone/isopropyl alcohol is introduced first. Subsequently, talc, magnesium stearate, titanium dioxide and pigments are added, followed by polyethylene glycol 6000 dissolved in water. This mixture is then finely dispersed by means of an Ultra-Turrax, added to a 12.5% solution of EUDRAGIT[®] L and homogenized in a double-cone mill. During spray application, both suspensions are thoroughly mixed by means of a pneumatic stirrer. A 12.5% solution of EUDRAGIT[®] L in isopropyl alcohol is available under the trade name of EUDRAGIT[®] L 12.5.

Such a solution is also easy to prepare from the solvent free solid EUDRAGIT[®] L 100. To this end, 13 parts by weight of EUDRAGIT[®] L 100 (= 12.5% dry polymer substance) are dissolved in a mixture of 82 wt. parts isopropyl alcohol and 5 wt. parts water at room temperature with stirring.

Typical formulation Enteric coating with EUDRAGIT[®] L 12.5**I. Base coat**

	Parts by weight
EUDRAGIT[®] L 12.5	2,000 g
Plasticizer	25 g
Talc	50 g
Isopropyl alcohol/acetone	1,925 g
	à 4,000 g

Solids content:	8.1%
Content in dry polymer substance:	6.3%

II. Top coat (coloured)

	Parts by weight
EUDRAGIT[®] L 12.5	1,200 g
Talc	140 g
Magnesium stearate	40 g
Titanium dioxide	50 g
Pigment	50 g
Polyethylene glycol 6000	20 g
Water	40 g
Isopropyl alcohol/acetone	1,460 g
	à 3,000 g

Solids content:	11.1%
Content in dry polymer substance:	5.7%

Operating data

Example

EUDRAGIT® L/S

Technical data

Coating unit	Brucks coating pan, stainless steel, Ø 500 mm, angle of inclination 30°
Feed pump	peristaltic pump with silicone tube, internal Ø 4 mm
Spray system	Walther Zenith pneumatic spray gun, nozzle Ø 1,5 mm (round spray)
Distance nozzle/tablets	120 mm

Coating data

Tablets	placebo cores, directly compressed, Ø 8 mm , 4 mm in height, 200 g in weight; 70% lactose, 10% corn starch, 20% microcrystalline cellulose; hardness 40 N, friability 1% (100 rev. in 4 min); disintegration time in demineralized H ₂ O: 30 sec.
Batch size	10 kg
Spray suspension	8,000 g, corresponding to 885 g solids or 8.85 wt.-% an tablet quantity, 457 g polymer equivalent to 4.6 wt.-% an tablet quantity ratio 1 : 1 to other excipients

Process data

	Preheating	Spraying	Polishing	Glossing	Drying
Duration	3 min	160 min	2 min	30 min	10 min
Inlet air quantity	1.5 m ³ /Min	1.5 m ³ /min	1.5 m ³ /min	-	1.5 m ³ /min
Inlet air temp.	50 °C	50 °C	50 °C	-	50 °C
Tablet temp.	30 °C	20-25 °C	20-25 °C	-	-
Pan speed	10 rpm	30 rpm	30 rpm	10 rpm	10 rpm
Pump speed	-	50 rpm	25 rpm	-	-
Atomizing air pressure	-	0.5 bar	0.5 bar	-	-
Spray rate	-	50 g/min	25 g/min	-	-

Other process data

Spray rate	5 g suspension/min/kg product = 0.55 g solids/min/kg product
Evaporation rate	4.45 g/min/kg product
Polymer quantity	4.6 mg/cm ²
Spraying process	continuous
Total process time	3 hrs 25 min
Polishing	with 50 g of a 10% solution of polyethylene glycol 6000 in a 1 : 1 acetone/water mixture
Post-drying	on trays at room temperature overnight or in drying cabinet within 2 hours at 40 °C

Results

Appearance	uniform, smooth and glossy coating
Gastroresistance	for 2 hours, then disintegration in intestinal fluid within max 15 min; no loss of enteric property after friability test
Shelf life	no change after storage for over 4 months at 65 °C or 37 °C and 80% RH, or after storage for 22 months at room temperature

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