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Röhm Pharma Polymers

Enteric coatings with EUDRAGIT â L/S from organic solutions.
Tablets coated by fluid-bed process

Spraying process for the manufacture a coating of colourless enteric sealing coats with EUDRAGIT® L 12.5 on tablets.

Operating method
The coating suspension is sprayed onto the fluidized tablets, which are prewarmed to about 30 °C, by means of built-in air nozzles (bottom-spray method). 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 25 to 30 °C and be able to flow freely.
Twinning, i.e. sticking together of tablets, can be avoided by adding suitable glidants (talc, magnesium stearate, kaolin, Syloid®) to the EUDRAGIT® L 12.5 spray suspension.
If twinning does occur, spraying must be interrupted until the tablets are dry and once more able to flow freely. Subsequently, processing may be continued at a reduced spray rate.

The following formulation gives the polymer and excipient quantities required for coating 1 kg of mediumsized tablets (diameter 11 mm, weight 640 mg) at a polymer weight of 8.1 mg/cm^2.

The solids are combined with the acetone and EUDRAGIT® L 12.5 and are then finely dispersed in a doublecone mill.

EUDRAGIT® L 12.5 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 from organic solution	
	Parts by weight
EUDRAGIT® L 12.5	440 g
Plasticizer	5 g
Talc	15 g
Elcema® P 050	5 g
Acetone	535 g
	å **1,000 g**
Solids content:	8.0%
Content in dry polymer substance:	5.5%

This gives a polymer (55 g from 440 g EUDRAGIT® L 12.5) weight of L = 8.1 mg/cm² by a tablet surface of S = 432 mm².
Where delayed release in the intestine is required in addition to resistance to gastric fluid, EUDRAGIT® L can be partially or completely replaced with EUDRAGIT® S.

Dosage forms with pH-independent delayed release of the active ingredient are obtained by using EUDRAGIT® RL/RS as the film formers. If organic solvents must be avoided altogether, the aqueous dispersion EUDRAGIT® L 30 D-55 is a suitable alternative.

Operating data

Example **EUDRAGIT® L/S**

Technical data

Coating unit	Aeromatic STREA-1 single-chamber fluidized-bed coater, bottom-spray
Feed pump	peristaltic pump with silicone tube, internal dia. 3 mm
Spray system	air spray gun, nozzle dia. 1.1 mm (round spray)
distance nozzle/tablets	120 mm

Coating data

Tablets	active cores, 11 mm in dia., 7 mm in height, 640 g in weight; hardness 70 N, disintegration time in demineralized H2O: 30 sec
Batch size	1 kg
Spray suspension	620 g, corresponding to 50 g solids or 5 wt.-% an tablet quantity, 34 g polymer equivalent to 3.4 wt.-% on tablet quantity, ratio 2:1 to other excipients

Process data	**Preheating**	**Spraying**	**Drying**
Duration	2 min	21 min	3 min
Inlet air quantity	-	2 m^3/min	1.6 m^3/min
Inlet air temperature	37 °C	36 °C	36 °C
Air inlet setting	5	13	11
Outlet air temperature	30 °C	29 °C	30 °C
Tablet temperature	30 °C	29 °C	30 °C
Pump speed	-	10 rpm	-
Atomizing air pressure	2 bar	2 bar	2 bar
Spray rate	-	30 g/min	-

Other process data

Spray rate	30 g suspension/min/kg product = 2.38 g solids/min/kg product
Evaporation rate	27.1 g/min/kg product
Polymer quantity	5.0 mg/cm2
Spraying process	continuous
Total process time	26 min
Post-drying	2 hrs on trays, in drying cabinet at 40 °C

Results

Appearance	uniform coating of subdued gloss
Gastroresistance	for 3 hours (BP), disintegration in intestinal fluid (BP): max. 45 min