

## Coating Parameters for the Use of Acryl-EZE® II

Acryl-EZE® II is a fully formulated, dry acrylic-enteric coating system, dispersible in water, for the application of a delayed release film coating to solid dosage forms such as tablets, granules and beads.

Combining the benefits of a fully formulated coating system with a globally accepted delayed release polymer, EUDRAGIT® L100-55, Acryl-EZE II is readily dispersible in water for easy application. The coating system can be pigmented to meet marketing requirements and provides consistent, reproducible delayed release profiles.

The coating parameters which are recommended for use with Acryl-EZE II are based on Colorcon trial data. Individual product and machine functions should be taken into account and conditions altered as required. For further technical advice, please contact your Colorcon Area Technical Manager.

Coating Parameter	O'Hara 24" Pan	O'Hara 30" Pan	O'Hara 48" Pan	Accela-Cota 150	Accela-Cota 60 DXL
Solvent	Distilled Water	Distilled Water	Distilled Water	Distilled Water	Distilled Water
Solids content (%w/w)	20	20	20	20	20
Theoretical weight gain (%)	7-10	7-10	7-10	7-10	7-10
Tablet charge (kg)	15	40	140	120	360
Inlet air temperature (°C)	55	46	53	53	54
Drying air volume (cfm)	250 (425 m <sup>3</sup> /hr)	550 (935 m <sup>3</sup> /hr)	1530 (2600 m <sup>3</sup> /hr)	1530 (2600 m <sup>3</sup> /hr)	4000 (6800 m <sup>3</sup> /hr)
Tablet surface bed temperature (°C)	29-35	29-35	29-32	29-35	29-36
Exhaust air temperature (°C)	32-34	30-35	34-38	36-38	37-40
Pre-warm tablet bed (°C)	34-36	34-36	34-36	34-36	34-36
Spray equipment	2 X SSVAU	2 X SSVAU	4 X SSUVAU	4 X Manesty	5 X JAU
Fluid nozzle (mm)	1.5	1.5	1.5	1.2	1.5
Air cap (mm)	3.3	3.3	3.3	4	3.4
Atomizing air pressure <sup>(1)</sup> (psi)	35 (2.4 bar)	45 (3 bar)	40 (2.8 bar)	45 (3 bar)	50 (3.6 bar)
Pattern air pressure <sup>(1)</sup> (psi)	35(2.4 bar)	40 (2.8 bar)	30 (2.1 bar)	35 (2.5 bar)	N/A
Gun-to-bed distance (inches)	5.5-6 (14-15cm)	7-7.5 (18-19cm)	8-8.5 (21-23cm)	9-9.5 (23-24cm)	10-12 (25-30cm)
Spray rate (g/min)	55-60	115-120	350	320	500-600
Baffles	2	2	4	4	4
Pan speed (rpm)	12	8	6-8	7	3.5-4.5

**(1) Adjust to maximize efficiency**

Acryl-EZE is reconstituted to 20% w/w solids dispersion for use. Recommended weight gains of Acryl-EZE are 7% to 10% for delayed release performance depending on the core. A sub-coat may be required to separate alkaline drugs from the enteric polymer or to strengthen the dosage form prior to enteric coating.

A top-coat may be used for additional gloss or to aid in printing.

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