

Coating Parameters for the Use of Acryl-EZE[®] MP -- Enteric Protection for Multi-Particulates

Acryl-EZE MP is a fully formulated, dry acrylic-enteric coating system, 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 MP 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 MP 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 Technical Representative.

Coating Parameter	GPCG-3	GPCG-3	Freund-Vector		
			VFC-60M with Wurster Accelerator		
Solvent	Distilled water	Distilled water	Distilled water	Distilled water	Distilled water
Solids content (% w/w)	20	20	20	20	20
Theoretical weight gain (%)	10	20	25	25	15
Substrate	Diclofenac Bead	ASA Bead	ASA Crystal	ASA Bead	Diclofenac Bead
Substrate mesh	14-25	30	50	30	14-25
Substrate charge (kg)	2.5	2.5	40	40	40
Inlet air temperature (°C)	49	48-51	67	64	50
Drying air volume (m ³ /hr)	210	139-152	497	625	1100
Air velocity (m/s)	8-12	8-9.5	N/A	N/A	N/A
Product temperature (°C)	32	30-32	30	29	30
Exhaust air temperature (°C)	30-32	30-33	26-30	26-30	25-30
Spray equipment	Schlick	Schlick	Schlick 0/4	Schlick 0/4	Schlick 0/4
Partition Height (cm)	2.0	2.0	3.8	2.5	2.5
Fluid nozzle (mm)	1.1	1.1	2.2	2.2	2.2
Air cap (mm)	2.0	2.0	9.0	9.0	9.0
Atomizing air pressure (bar)	2	2	1.5	2	2
Spray rate (g/min)	20	20-21	220	270	290

Acryl-EZE MP is reconstituted to 20% w/w solids dispersion for use. Recommended weight gains of Acryl-EZE MP start at 10% for enteric performance depending on the shape, size and surface area of the multiparticulate. A sub-coat may be required to separate strongly acidic or basic drugs from the enteric polymer or to strengthen the dosage form prior to enteric coating. A colored top-coat may be applied if required.

* Methacrylic acid copolymer type C

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