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

Acryl-EZE II 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 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 Technical Representative.

| Coating Parameter | Glatt GPCG-1.1 | Glatt GPCG-2 | Glatt GPCG-3 | Freund-Vector VFC-60M with Wurster Accelerator |
|---|---|---|---|---|
| **Solvent** | Distilled water | Distilled water | Distilled water | Distilled water |
| **Solids content (% w/w)** | 20 | 20 | 20 | 20 |
| **Theoretical weight gain (%)** | 25 | 20-40 | 25 | 20-40 |
| **Substrate** | SUGLETS® | Lansoprazole MP | SUGLETS® | Lansoprazole MP |
| **Substrate mesh** | 30-35 | 18-20 | 30-35 | 18-20 |
| **Substrate charge (kg)** | 0.6 | 2 | 2.5 | 50 |
| **Inlet air temperature (°C)** | 55 | 55 | 45 | 65 |
| **Drying air volume ($m^3$/hr)** | 70 | 130 | 130 | 1359 |
| **Product temperature (°C)** | 33 | 35 | 33 | 35 |
| **Exhaust air temperature (°C)** | 32 | 35 | 34 | 35 |
| **Spray equipment** | Schlick 970 | Schlick 970 | Schlick 970 | Schlick 0/4 |
| **Partition Height (cm)** | 2.0 | 1.8 | 1.8 | 4.6 |
| **Fluid nozzle (mm)** | 1.1 | 1.1 | 1.0 | 2.2 |
| **Air cap (mm)** | 2.0 | 2.0 | 2.0 | 9.0 |
| **Atomizing air pressure (bar)** | 1.8 | 2 | 2.5 | 3 |
| **Spray rate (g/min)** | 13 | 12-15 | 15 | 250 |

Acryl-EZE II is reconstituted to 20% w/w solids dispersion for use. Recommended weight gains of Acryl-EZE II start at 20% 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



For more information, contact your Colorcon representative or call:

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