

Evaluation of a New Film-Coating System for Temperature Sensitive Active Pharmaceutical Ingredients

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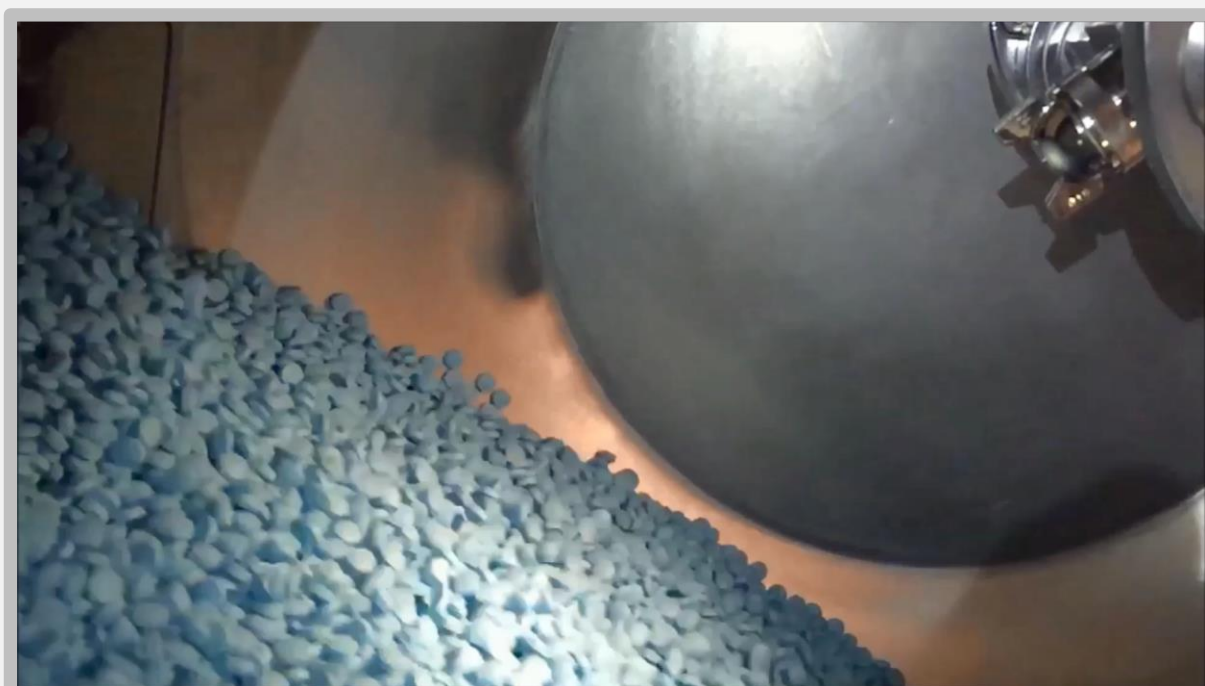
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Purpose

Many API's and excipients are heat sensitive. This can prove problematic when using regular film coating systems based on HPMC or PVA because high temperatures are required in order to efficiently apply a uniform coating. If the elevated temperatures are not used, a variety of issues related to over-wetting may occur. The objective of this study was to evaluate the performance of a modified pea starch polymer based coating formulation processed at a tablet bed temperature lower than 25 C.

Methods

500 mg, standard cup, core tablets (lactose, microcrystalline cellulose, and magnesium stearate) were coated with an aqueous solution of the pea starch based coating (ReadiLycoat®, Roquette) at 20% solids concentration. Batch sizes of 35 kg were processed up to a 4% weight gain using a fully perforated, 55 liter coating pan (VHC-5811, Freund-Vector). The coating solution was applied with an AT manifold gun body equipped with a 1.2mm fluid tip and 015 air cap. Process parameters are listed in Table 1 and were aimed to achieve tablet bed temperatures in the range of 20°C-25°C. Color uniformity was evaluated visually, and via spectrophotometric ΔE values (ΔE is a positive number expressing a difference between two colors) using a Konica Minolta CM-5 spectrophotometer. Uncoated and coated tablet disintegration time was assayed on Dr. Schleuniger, DTG 2000, Pharmatron equipment.

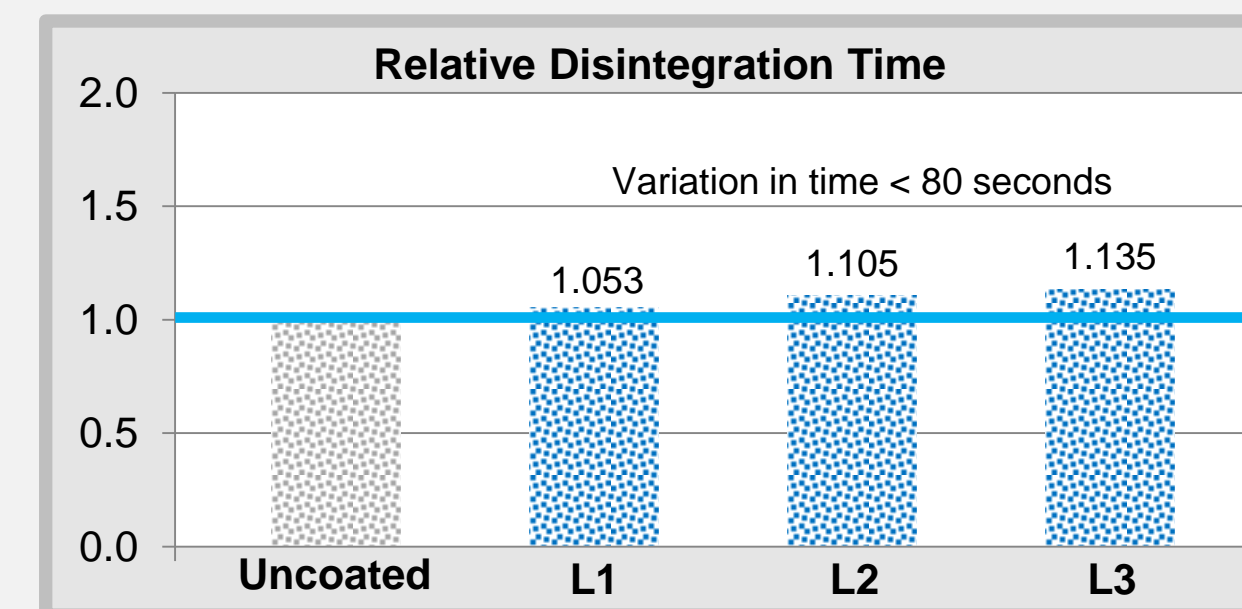
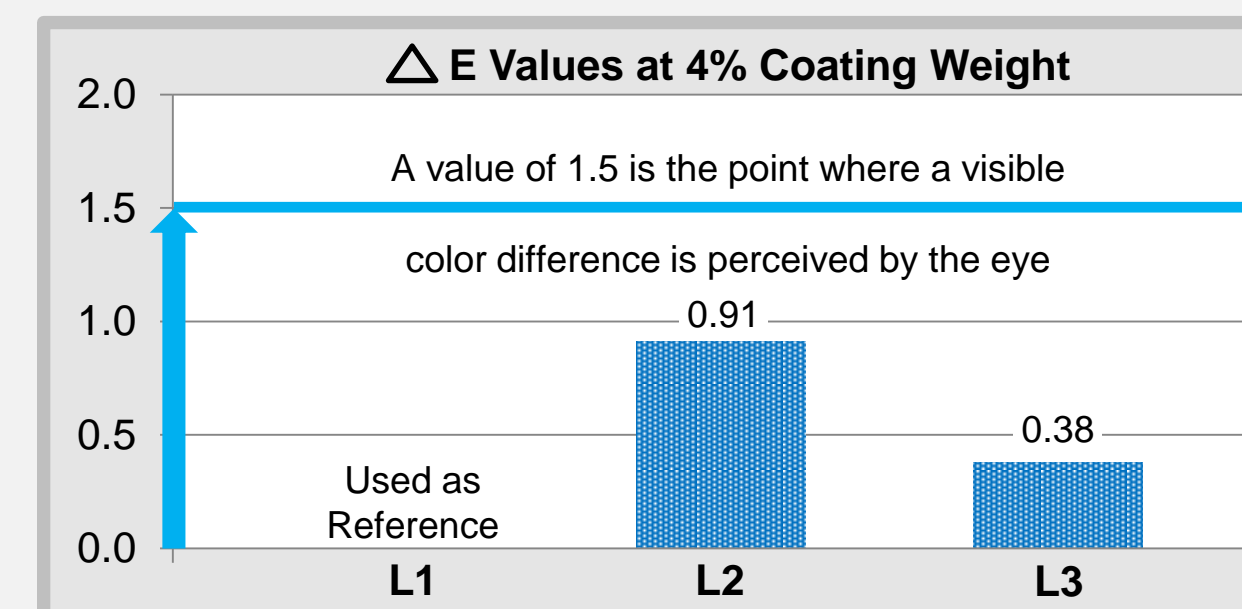


Methods

Table 1. Process Parameters

Parameter	Trial L1	Trial L2	Trial L3
Product Bed Temperature (C)	25	22	20
Inlet Air Temperature (C)	45	35	37
Inlet Air Flow (M3/H)	764	1019	764
Spray Rate (g/min)	81.4	81.7	80.8
Spray Gun to Tablet Bed (cm)	22	28	22
Atomization Air (SLPM)	100	100	100
Pattern Air (SLPM)	130	100	130
Final Coating %	4.0	4.0	4.0
Spray Time (min)	88.6	88.5	89.5
Pan Speed (rpm)	8	8	8
Batch Size (Kg)	35	35	35

Results



Conclusion

The novel combination of the coating system based on a modified pea starch polymer and low tablet bed temperatures proved to be an effective coating solution for heat sensitive API's. It produces a uniform, visually appealing coating while using standard film-coating equipment and only water as a solvent.