T3176

# Tablet Coating at Low Bed Temperatures with a Novel Coating Polymer

C. Popescu[1], T.J. Smith[2], B.K. Jensen[2], G. Le Bihan[3], X. Parissaux[3], S. Croquet[3], P. Lefevre[3]
[1]Roquette America Inc., Geneva, IL, USA; [2]Freund-Vector Corporation, Marion, IA, USA; [3]Roquette, Freres, France
carmen.popescu@roquette.com; tim.smith@freund-vector.com

## Introduction

Currently, when coating tablets with moisture sensitive actives, aqueous film coatings based on PEG, PVA, and HPMC are recommended to be applied at high product temperatures to overcome the API's sensitivity. Unfortunately, this approach can lead to heat degradation of the API and other potential physical tablet coating defects.

## Purpose

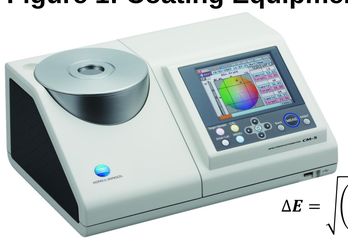
The goal of this study was to evaluate the coating quality of a modified pea starch based polymer in a ready to use coating formulation ( ReadiLycoat ® ) at a process bed temperature lower than 25 C.

## Material and Methods

2.5 kilograms core tablets (800mg, mannitol based) were processed with 20% dry solids coating formulation (ReadiLycoat ® , Roquette) to 3% and 4% coating by weight using a fully perforated 4 liters coating pan (LDCS, Freund-Vector Corporation) equipped with a spray gun utilizing a Schlick 1.0 mm fluid tip and ATB air cap (see Figure 1). Coating parameters are shown in Table 1. 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 (see Figure 2). .

Freund-Vector
Laboratory Development Coating System
(LDCS)
with 4 liter coating pan

**Figure 1: Coating Equipment**



L*, a*, and b* values for SCI
(Specular Component Included)
were used to calculate the
ΔE CIE 2000 (1.1.1) values:

$$\Delta E = \sqrt{\left(\frac{\Delta L'}{K_L S_L}\right)^2 + \left(\frac{\Delta C'}{K_C S_C}\right)^2 + \left(\frac{\Delta H'}{K_H S_H}\right)^2 + R_T \left(\frac{\Delta C'}{K_C S_C}\right)\left(\frac{\Delta H'}{K_H S_H}\right)}$$

**Figure 2: Spectrophotometric Equipment / Method**

## Results

**Table 1: Coating Parameters**

| Parameter | Trial T2-2 | Trial T2-3 | Trial T2-4 | Trial T2-5 | Trial T2-6 |
|---|---|---|---|---|---|
| Batch Size (Kg) | 2.5 | 2.5 | 2.5 | 2.5 | 2.5 |
| Inlet Air Temperature (C) | 57-60 | 60-62 | 42-47 | 37-42 | 30-35 |
| Inlet Air Flow (M3/H) | 100 | 68 | 68 | 68 | 100 |
| Spray Rate (g/min) | 10.0 | 10.4 | 10.4 | 10.5 | 8.2 |
| Atomization Air (bar) | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |
| Pattern Air (bar) | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |
| Spray Gun to Tablet Bed (cm) | 10 | 10 | 10 | 10 | 10 |
| Final Coating % | 4.0 | 3.9 | 4.1 | 4.0 | 4.0 |
| Spray Time (min) | 51.9 | 48.5 | 52.0 | 49.9 | 63.3 |
| Pan Speed (rpm) | 18 | 18 | 18 | 18 | 18 |
| Product Bed Temperature (C) | 40-43 | 37-38 | 24-28 | 20-25 | 19-22 |

**Figure 3: Final Coated Product**

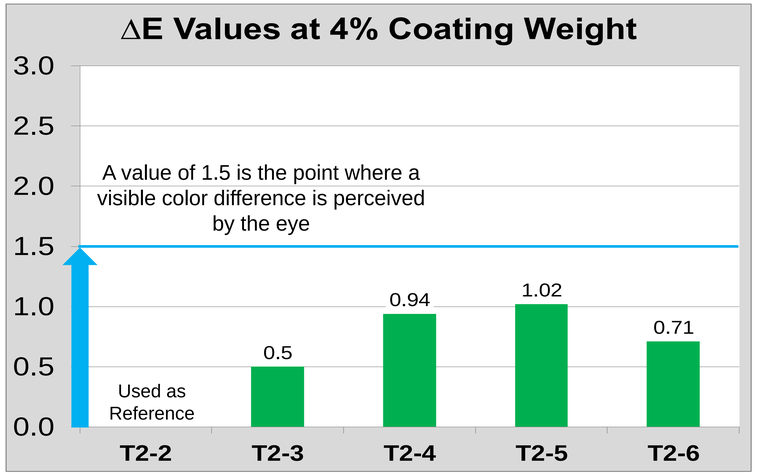



**Figure 4: Color Uniformity**

Notes:
1) Tablets from Trial 2-2 were used as the reference tablets for ΔE values
2) Trial T2-3 tablets were also compared at 3% coating weight and had a ΔE=0.86

## Discussion

- Coated tablets had ΔE values in the range of 0.5-1.0, resulting in a tablet appealing with very good color uniformity and visually appealing
- Friability measurements resulted in 0% loss of tablet/coating weight.
- Disintegration times for coated tablets compared to uncoated tablets increased only 39 seconds (86 seconds to 125 seconds).

## Conclusion

The novel combination of the modified pea starch polymer with high solids content and low tablet bed temperature makes possible:

- Elegant, uniform coatings with zero visible defects
- A practical coating solution for APIs with stability issues

## Reference

ΔE values were calculated using the Color Difference Calculator found at
http://www.brucelindbloom.com/index.html?Eqn_DeltaE_CIE2000.html