Sensient Pharmaceutical Coating Systems offers novel film coating systems that are widely used in the industry. One of the newer coating systems is patented Spectrablend CC (calcium carbonate). Spectrablend CC is a metal free coating system free of titanium dioxide exhibiting hiding power in high solids, non-foaming solutions. Other attributes are the incorporation of natural colors for the nutraceutical companies and iron oxides for the pharmaceutical companies affording smooth, glossy and defined logo definitions.

**INTRODUCTION**

The state of California (CA) published a Notice of Intent to list Titanium Dioxide under Proposition 65 using the Labor Code mechanism on May 27, 2011. On September 2, 2011, CA officially listed Titanium Dioxide under Proposition 65. Sensient is taking a proactive step in offering Calcium Carbonate as an alternative to Titanium Dioxide in coating systems.

The calcium carbonate (CaCO$_3$) film coating system requires hiding power to mask core visual imperfections. Hiding power/opacity was evaluated by optimizing the weight gain preferentially with selected calcium carbonate grades. The morphology and particle size of selected calcium carbonate grades provides hiding power results herein. Particle size measurements were taken with a Malvern Mastersizer MS2000 using a Scirroco dry dispersion unit. Morphological surfaces were evaluated through scanning electron microscopic (SEM) imagery in order to understand surface rheology, light reflection and light refraction.

As a complete film coating system, Spectrablend CC incorporates natural colored pigments for the nutraceutical industry and iron oxides for the pharmaceutical industry. Natural colors are more readily stabilized in a calcium carbonate medium due to divalency augmenting color stability. Anthocyanins can now be used to form stable green and blue pigments for the nutraceutical companies. Pharmaceutical companies can utilize Spectrablend CC by incorporating FDA approved iron oxides into the matrix blend. The surface morphology of iron oxides exhibits unique gloss effects through light reflectance and refraction.

**EXPERIMENTAL METHODS**

The calcium carbonate particle size distribution (psd) was analyzed on the Malvern and was compared to the particle size of Titanium dioxide (0.3 to 5 microns). Two grades of calcium carbonate were evaluated; a precipitated grade (Figure 1) and a ground grade (Figure 2).

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**Figure 1 Precipitated CaCO$_3$**

Figure 1 depicts a particle size range of precipitated calcium carbonate (PCC) between 2.461µm to 7.437µm (d50 = 4.264µm).

**Figure 2 Ground CaCO$_3$**

Figure 2 depicts ground CaCO$_3$ psd analysis range between 2.033µm and 19.208µm (d50 = 7.682µm). Comparing the psd analysis shows similarities between the particle size of ground calcium carbonate and Titanium Dioxide where Titanium dioxide has a broader range of 0.3 µm to 5µm. The broader range would provide better hiding power with smaller particles filling in open regions of the matrix.

The psd was not the only determining factor in choosing ground CaCO$_3$ over the precipitated CaCO$_3$. Understanding the light reflectance inherently affects the coating gloss. The light will reflect off a smoother surface (Figure 3: Ground CaCO$_3$ (GCC)); whereas, the light will refract and bend in different directions on an uneven surface and jagged edges (Figure 4: PCC CaCO$_3$).

**Figure 3: Ground CaCO$_3$ (GCC)**

**Figure 4: PCC CaCO$_3$**

Figure 3 and Figure 4 have a distinctive morphological difference between GCC (Figure 3) and PCC (Figure 4).
Figure 4: Precipitated \( \text{CaCO}_3 \) (PCC) 

Figure 4 illustrates highly ordered crystalline particles which can interrupt direct reflectance.

Figure 5: Reflection and Refraction

Figure 5 illustrates the incidence of light, and the more crystalline the particle, the greater the refraction will be. Thus, refraction influences dulling effects on the surface. For this reason GCC’s flatter surface will reflect light proportionally to the angle of incidence affording a glossy finish. This explains the higher gloss of Spectrablend CC using ground calcium carbonate.

Coating weight gains were evaluated for hiding power efficiencies (opacity). Three different iron oxides were utilized in the Spectrablend CC formulations consisting of black, red and yellow. The partial tablet image in Figure 5 utilized GCC and red iron oxide.

Figure 5: Spectrablend CC – Red Iron Oxide Coating

Figure 5 illustrates the smooth logo definition at three percent weight gain. Figure 6 depicts core coverage relative to percent coated weight gain.

Figure 6: Spectrablend CC – Yellow Iron Oxide

Figure 6 depicts the effect of 4, 6, 8 and 10 percent weight gains with Spectrablend CC yellow iron oxide coated onto white, dark and vitamin type cores. It is learned from figure 6 that white cores only need 4% weight gain, while 6% to 8% weight gains are required for dark and mottled cores. Figure 7 illustrates a Leneta draw down card in the middle and two tablets coated to 3% wt gain using the same formula with Black Iron Oxide; however, replacing the \( \text{CaCO}_3 \) to depict a comparative analysis.

Figure 7: Use Test Comparing GCC vs PCC \( \text{CaCO}_3 \)

Figure 7 illustrates the surface rheology comparison having similar hiding power effects. The depth of color is more pronounced utilizing GCC which is indicative of reflection influences.

RESULTS AND DISCUSSION

This study shows GCC and PCC morphologies and psd are important aspects to providing hiding power and promoting color definition while maintaining clear logos.

CONCLUSION

Sensient’s patent pending; Spectrablend™ CC provides an excellent alternative to titanium dioxide for hiding power effects on tablet film coatings. The premium performance and visual enhancements are desirable for both; nutraceutical and pharmaceutical companies. Pharmaceutical companies can utilize ground calcium carbonate coatings with iron oxides for enhanced color tones on immediate release marketed products.

REFERENCES


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