tablet coating

Evaluation of a continuous-cycled film coater in applying a high-solids coating formulation

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The study described here evaluated the performance of a novel film coating formulation that can be applied at solids concentrations as great as 35 percent in a continuous-cycled coating process. Four trials were conducted and the coated tablets were assessed for weight gain consistency, color uniformity, surface roughness, and gloss.

Continuous film coating processes can shorten coating times and provide excellent color uniformity because they use shallower tablet beds than the traditional batch process, and the tablets pass through the spray zone more frequently [1]. In traditional batch coaters, as the scale of the coating process increases, the diameter of the coating pan increases, as does the depth of the tablet bed and the number of tablets isolated from the spray zone at any given time. This is a fixed constraint of batch coating processes.

Elongated (up to15 feet) continuous coating machines, however, use pans that are half the diameter (or less) of manufacturing-scale batch coaters [2]. Furthermore, the tablet bed depth of elongated coaters is closer to that of laboratory- and pilot-scale batch coating pans. As interest in continuous processing grows, coating equipment manufacturers are developing more options for continuous film coating. One machine, Driaconti-T Pharma (Driam, Eriskirch, Germany), is a continuous-cycled coater that combines the attributes of continuous processing with the advantages of small-scale batch production. It achieves this by using a segmented chamber [3].

One potential limitation of continuous coating is the difficulty of applying the requisite amount of coating during the shorter period that the tablets reside in the pan (typically 10 to 15 minutes). It has been proposed that coating formulations with a high solids concentration (25 percent or more) may mitigate this concern without the need to reduce throughput [4, 5].

The study described here evaluated the performance of a novel film coating formulation that can be applied at solids concentrations as great as 35 percent in a continuous-cycled coating process.

Methods

Equipment. The coating evaluations were conducted in a Driaconti-T Pharma continuous-cycled coating machine (photo next page). The machine is equipped with a perforated, 100-centimeter-diameter rotating drum. The drum, 154 centimeters long, has seven coating chambers spaced 22 centimeters apart that are separated by walls 30 centimeters high.

The process begins in a warming hopper that raises the temperature of the tablets as needed and then releases them into the first chamber in "mini-batches." Each mini-batch moves from chamber to chamber after the machine applies the specified amount of film coating. Typically, tablets in each chamber are coated to one-seventh of the target final coating weight gain (WG). Once the tablets are sufficiently coated, pneumatically operated flaps built into the walls separating the chambers open the full width of the chamber, forming a helix that conveys the tablets from one chamber to the next with a single rotation of the pan. The flap then closes and the next spray sequence begins.

Each of the seven chambers includes a spray gun (Schlick 970 ABC, 1.0-millimeter nozzle tip, Düsen-Schlick, Untersiemau, Germany) mounted so that it sprays directly on the tablets. To deliver the coating dispersion to the spray guns, the coater uses a bank of seven peristaltic pumps (Watson Marlow, Falmouth, UK)

Driam's Driaconti-T Pharma

mounted on a cart at the machine's front. Each pump is controlled separately, which allows sequencing of the spray guns as the chambers fill during startup and as they empty during shutdown. If desired, the separate controls can be used to apply different WGs at each chamber or apply two different coatings in the same process. For instance, a gloss coat could be applied in the final chamber. Figure 1 illustrates the machine's configuration and the photo on page 20 shows the coating chambers.

Visually, tablets bearing a higher-solids coating were virtually indistinguishable from those coated with a lower-solids formulation.

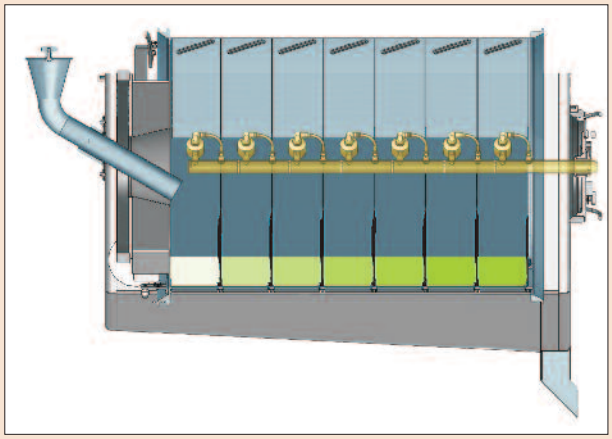
The multi-chamber configuration, coupled with individual spray gun control, also allow researchers to run trial batches in a single chamber to understand how different parameter settings affect performance before scaling up to full production.

Coating formulation and preparation. The study used a new, pigmented coating formulation developed by Colorcon and based on a polyvinyl alcohol-polyethylene glycol graft copolymer (Kollicoat IR, BASF, Florham Park, NJ). This developmental coating system, designed for aqueous application at high solids concentrations, exhibits very low viscosity (Figure 2). Typically, it is recommended that coating formulations not exceed 450 to 500 centipoise so that they can be easily pumped and so that they form adequate droplets. For each trial—depending on the specified solids concentration—the fully formulated dry powder mix was added to water using a standard propeller mixer with moderate agitation. Once all the powder was added to the water, the impeller's speed was reduced and the coating was gently mixed for 30 minutes before use.

Coating trials and parameters. Four trials were conducted to assess how increasing the coating's solids concentration affected throughput, coating uniformity, and

FIGURE 1

Driaconti-T Pharma configuration



tablet surface properties. Round, 10-millimeter placebo tablets weighing 300 milligrams and debossed with Colorcon's logo were used in the trials. The target coating WG was 3.0 percent. As the solids concentration of the coating formulation for each trial increased, tablet throughput was increased proportionally to achieve the target WG. All other coating parameters were held constant (Table 1).

Coating uniformity assessments. Tracer tablets were used to determine coating WG and variation as the mini-batches of tablets passed through the coating chambers. Each tracer tablet bore a unique letter and number written with a black marker. The marked tablets were dried to a constant weight in a 50°C oven. After drying, the weight of each tablet was recorded.

For each trial, the coating process was allowed to run

FIGURE 2

Viscosity profile of the coating formulation

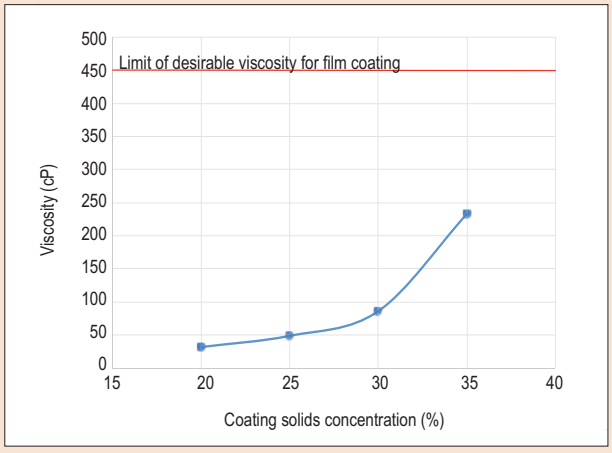


TABLE 1

Coating process parameters

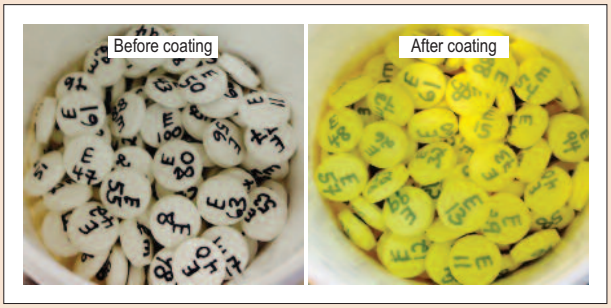
Process parameter	Trial 1	Trial 2	Trial 3	Trial 4
Coating solids concentration (%)	20.0	25.0	30.0	35.0
Resident pan load (kg)	126			
Load per chamber (kg)	18			
Process air volume (m3/h)	3,500			
Inlet temperature (C°)	68-73			
Exhaust temperature (C°)	48-50			
Product temperature (C°)	42-46			
Spray rate per chamber (g/min)	44			
Atomizing air pressure (bar)	1.1			
Pattern air pressure (bar)	0.5			
Pan speed - coating (rpm)	8.0			
Pan speed - product transfer (min)	2.0			
Coating time per cycle (min)	8.8	7.0	5.8	5.0
Product transfer time per cycle (min)	0.9	0.9	0.9	0.9
Total tablet throughput rate (kg/hr)	110.2	135.0	158.8	180.0

until all chambers were full and the first coated tablets began discharging from the pan. While the machine was running in full semi-continuous mode, the first set of 50 marked tablets was added to the 18 kilograms of tablets in the warming hopper. As the process continued, additional sets of 50 marked tablets were added to each incoming mini-batch until every chamber contained a set of marked tablets. The coating process was run until the first set of marked tablets reached the final chamber's discharge. At that point, the process was stopped and each chamber was emptied sequentially into separate collection bags. Next, the tracer tablets were removed from the collection bags. The tracer tablets were easy to find even after a 3 percent WG of coating because the coating formulation used a low level of D&C Yellow #10 and the markings were obvious (Figure 3).

The recovered tracer tablets were again dried to constant weight and reweighed to determine the actual WG percentage for each tablet, as well as the coating weight variation among each set of marked tablets. Drying the tablets to constant weight before and after coating ensured that any moisture gain or loss induced by the coating process would not affect the accuracy of the WG measurement. The marked tablets provided a means to assess the consistency of WG from chamber to chamber.

FIGURE 3

Tracer tablets before and after coating



Appearance of coated tablets. Samples taken from each coating chamber at the end of each trial were assessed visually and tested for color uniformity (Model 600, Datacolor, Lawrenceville, NJ), surface roughness using an optical scanning profilometer (Model PS50, Nanovea, Irvine, CA) and gloss (Model 805A Surface Analysis System, Tricor Systems, Elgin, IL).

Results and discussion

An automated system controlled all process parameters according to the settings (recipe) input for each trial. At startup, the first coating chamber was filled and the required amount of coating was applied to the first mini-batch. Upon completion of the spray cycle, the partially coated tablets transferred automatically into the next chamber, and the first chamber refilled. This sequence repeated until all chambers were full, and the fully coated tablets began discharging from the machine. Based on assessments of the marked tablets that were recovered after coating, it appeared that all tablets transferred into subsequent coating chambers without any comingling of the mini-batches.

During the trials, the time required to reach the target 3 percent WG decreased as the solids concentration of the coating increased. Tablet throughput rates ranged from 110 kilograms per hour at 20 percent solids concentration to 180 kilograms per hour at 35 percent solids concentration.

Color and weight uniformity. Each of the four trials produced coated tablets that were visually uniform in color. Because each trial was stopped before reaching the shutdown sequence, how color and coating weight developed could be characterized chamber by chamber. As expected, coating weight increased incrementally from chamber to chamber, while the difference in color from the reference tablet decreased. In all cases, the target color was obtained in the fourth coating chamber and, by the fifth coating chamber (WG of 2.2 to 2.5 percent), color uniformity was excellent, with very low standard deviation between samples. Figures 4 through 7 show actual WG and color uniformity trends.

Final coated tablet weight variation increased as solids concentrations increased because tablet throughput was higher, which reduced the time tablets spent in each chamber (Table 2). However, the highest variability—17.2 percent RSD when a 35 percent solids concentration was applied—was less than a previously reported value of 18.7 percent RSD when a 20 percent solids concentration of the same coating material was applied in a traditional 48-inch-diameter production-scale batch pan [5].

Appearance of coated tablets. Coated tablets from all

Figure 4

Color and weight development at 20 percent solids concentration

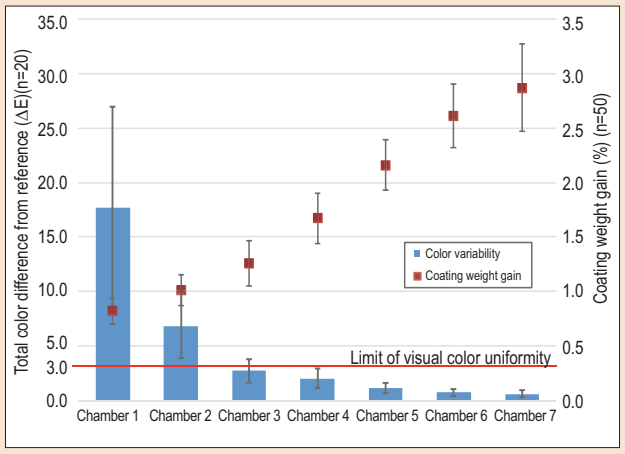


Figure 5

Color and weight development at 25 percent solids concentration

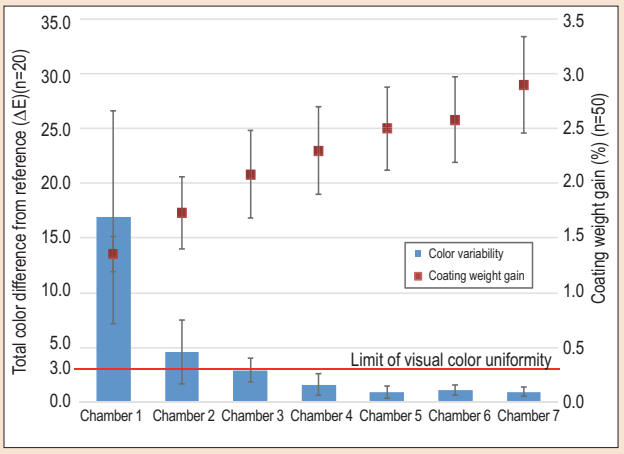


Figure 6

Color and weight development at 30 percent solids concentration

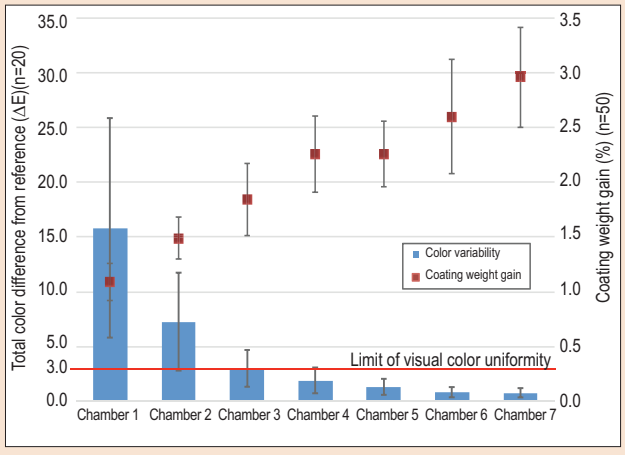
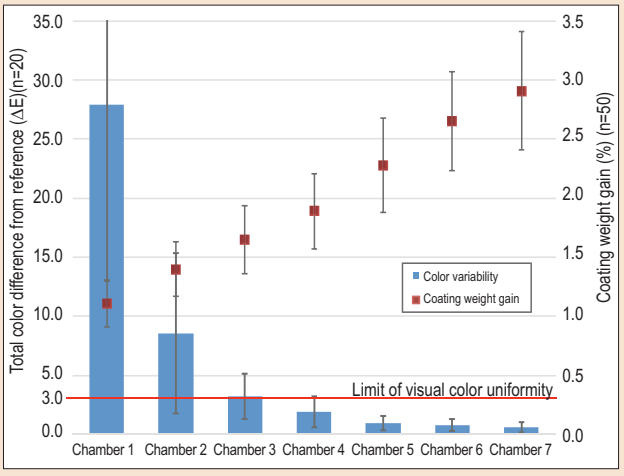


Figure 7

Color and weight development at 35 percent solids concentration



the trials were smooth and defect-free. Visually, tablets bearing a higher-solids coating were virtually indistinguishable from those coated with a lower-solids formulation. And logo definition was excellent, even when the tablets were coated at 35 percent solids concentration (photo next page).

The gloss of the coated tablets from each trial was very high, exceeding 100 gloss units (GU), but the instrument indicated that gloss decreased as the solids concentration increased. This trend is consistent with observations made in a Quality-by-Design study of film coating that evaluated gloss as a key aesthetic product attribute. That study, however, was limited to coatings that had a maximum 25 percent solids concentration, and gloss values greater than 100 GU were only achievable at solids concentrations of 20 percent or less [6].

Gloss can also be correlated to surface roughness, with smoother surfaces providing higher gloss as light reflectance increases. Surface roughness measurements of the coated tablets showed little if any effect of increasing the solids concentrations. In fact, in cases where some increase in roughness might be expected, a very slight decrease in roughness was measured for tablets coated with the higher solids concentrations compared to the lowest solids concentration. This result may be attributed to the very low viscosity and surface tension properties of the coating dispersion, which allow for efficient atomization, wetting, and spreading. Figure 8 shows the gloss and roughness values.

Conclusions

The Driaconti-T coater, with its unique method for conveying tablets through the coating process, produced coated tablets with excellent uniformity at coating solids concentrations as high as 35 percent. Another advantage of this machine is its ability to run test batches in a single chamber in order to determine the optimal process parameters for production-scale batches. The novel coating system used in these trials provided exceptional tablet appearance at solids concentrations of 20 to 35 percent.

Table 2

Variability in weights of coated tablets: Continuous versus batch

Solids concentration of coating dispersion (%)	Coating weight variability (% RSD) in Driaconti-T Pharma at 3% WG	Coating weight variability (% RSD) in traditional 48-inch batch pan at 3% WG
20.0	14.1	18.7
25.0	15.2	23.9
30.0	15.7	n/a
35.0	17.2	n/a

Appearance of tablets coated at 35 percent solids concentration

This flexibility in solids concentrations allows manufacturers to optimize the coating system to suit a range of processes, from traditional batch pan coaters to high-throughput continuous coaters. *T&C*

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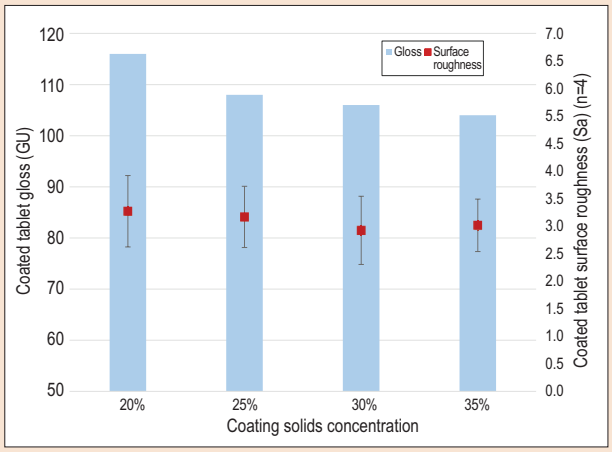
Figure 8

Gloss and surface roughness of coated tablets



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