Opadry® QX
Quick and Flexible Coating System

Colorcon®

Evaluating Continuous Coating Parameters and Their Effects on Appearance (Surface Roughness) Using a High Productivity Film Coating System

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Purpose

Continuous coating enables faster cycle times with increased process flexibility and throughput. Regulatory agencies, such as the U.S. Food and Drug Administration, also see the benefits in improving manufacturing processes to reduce production interruptions and product failures. Continuous coaters are designed to run for days without interruption, with tablet throughput ranging from 210 kg to 1000 kg per hour, and with large volumes of drying air, for example up to 10,000 CFM, and spray rates of over a liter per minute, through two spray manifolds. With growing interest in continuous processing for the pharmaceutical industry, developing guidelines for the optimal coating formulation and process conditions that will consistently result in production of high quality film coated tablets is needed.

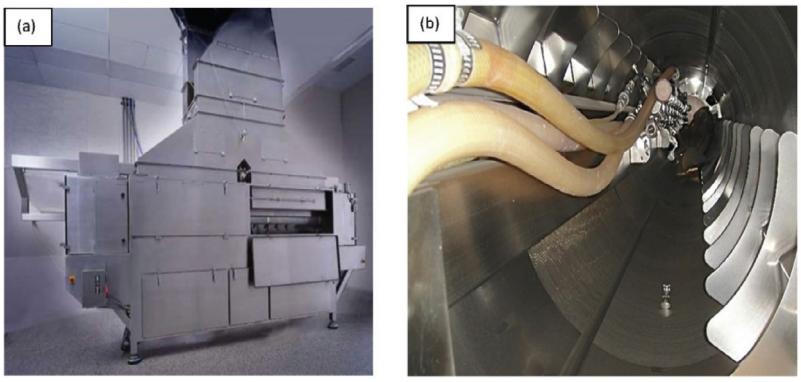
The purpose of this study was to evaluate the feasibility of Opadry® QX, quick and flexible film coating system (PVA-PEG graft polymer based) on a commercial-scale continuous coating line and to evaluate the effects of coating parameters on visual color uniformity, smoothness and elegant tablet appearance, and finally to compare the gloss of the tablets with those coated using a traditional batch process.

Methods

Debossed capsule shaped model drug tablets (650 mg), were aqueously film coated with Opadry QX, using a 24" diameter continuous tablet coater (Figure 1a). The film coating dispersion of Opadry QX was prepared at 20% solids concentration (w/w) and applied to a target weight gain (WG) of 3.5% (w/w) at tablet throughput rates of 3.5-4.5 kg/min.

The continuous coater was equipped with eighteen spray guns (1/4 JAU model, Spraying Systems Ltd), mounted on a manifold to ensure even dispersion of the coating suspension over the entire tablet bed (Figure 1b). The spray gun manifold was positioned at the four o'clock position. The method of mixing for this continuous coater was via four sets of plough shear type mixing baffles. A hand held infrared thermometer was used to monitor the product temperature throughout the trial.

Figure 1: (a) 24 " Continuous Coater (b) 2 -Spray Bar and Mixing Baffl e s Inside the Pan, Viewed from Infeed End



The coating trials were conducted using 1,200 kg of capsule shaped model drug tablet cores. Throughout the trials, drum speed (rpm), inlet airflow (CFM), atomization air (psi), and liquid infeed and outfeed spray rates (g/min) were varied, described as set points (Table 1). The inlet air temperature (°C) was adjusted to maintain the product temperature and exhaust temperature (Table 1). The range of test parameters were limited to the constraints of the commercial batch manufacturing record.

Table 1: Set Points for Coating Trials

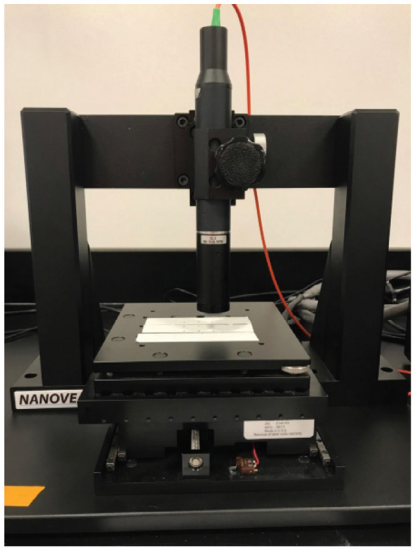
24" Continuous Coating Parameters									
Set Point	**Drum Speed (rpm)**	**Inlet Airflow (CFM)**	**Inlet Temp (°C)**	**Exhaust Temp (°C)**	**Tablet Bed Temp (°C)**	**Atomizing Air (psi)**	**Infeed Soln. Flow (g/min)**	**Outfeed Soln. Flow (g/min)**	**Tablet Throughput (kg/min)**
3	6.5	4800	61	51	37	55	400	400	3.6
4	6.5	4800	61	49	37	55	440	370	3.6
5	7	5100	62	50	42	55	440	370	3.9
6	7	5100	62	50	43	55	480	320	4.0
7	8	5100	62	50	44	55	480	360	4.5
8	7	5100	58	46	39	45	440	370	4.0
9	8	5100	58	47	35	45	450	400	4.3
36" Batch Coating Parameters									
1	10	950	57	43	37	45	180	NA	NA

(Set point #2 samples were not available for testing)

The coating suspension was applied through two manifolds; the infeed and the outfeed, which is a typical set-up for continuous coater. Samples were collected after a specific equilibration time for each set point. The references trial was conducted in a 36" perforated batch coater (52 kg pan load) at a target coating weight gain of 3.5% (w/w), with a process time of 50 minutes.

An optical scanning profilometer (Model CRS-50XY, Nanovea, USA) was used to measure surface roughness (a) for the samples collected (Figure 2).

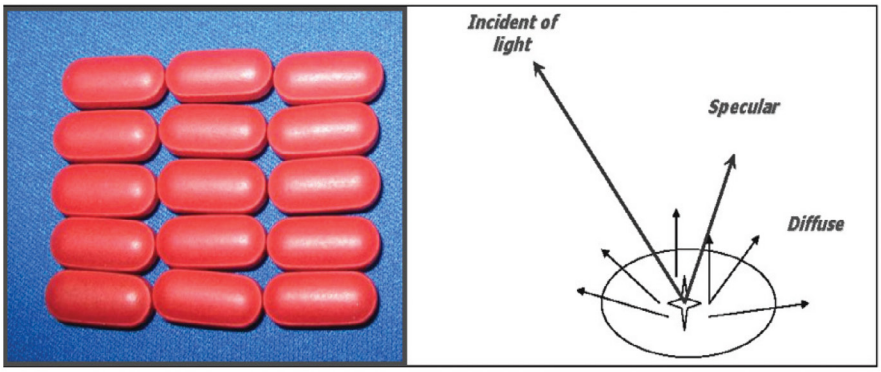
Figure 2: Nanovea Optical Scanning Profilometer



The gloss level of sample tablets was measured using a Model 805A Gloss/Surface Analysis System (Tricor Systems, Inc., USA). The quantity of light reflected at a 60° angle is reported as gloss units (GU) (Figure 3).

Figure 3: Gloss Measurement Method

Gloss is determined by projecting a beam of light at a fixed intensity and angle onto a surface and measuring the amount of reflected light at an equal but opposite angle. Several tablets are analyzed to occupy the field of vision of the gloss meter.



Results

An acceptable quality limit (AQL) test was applied with results passing at all set points studied on the continuous coater and batch coater. Visual examination of color uniformity and logo clarity were satisfactory within all process parameters studied on the continuous coater. When comparing tablets from continuous and batch coaters, reference trial tablets (36" batch coater) exhibited lower surface roughness (Figure 4).

This difference in surface roughness is most likely due to drying dynamics between the continuous and batch coaters, and the fact that the tablets were held in the 36" batch coater for cooling at the end of the coating process, which results in polishing of the coated tablets. A similar trend is observed with gloss, where the batch coater produced a glossier finish, again related to the polishing that occurs during product cooling (Figure 5).

While the gloss for the tablets from the continuous coater was lower than reference tablets, all continuous coated tablets did meet the AQL. Additionally, tablet throughput was significantly higher for continuous coating with a production rate of >200 kg/hr. To yield the same tablet output in the 36" batch coater, it would be necessary to complete at least four traditional batch coatings at 50 min each for a total of 3.5 hrs, without accounting for loading and discharge, compared to 1 hr in the continuous coater.

Figure 4: Surface Roughness

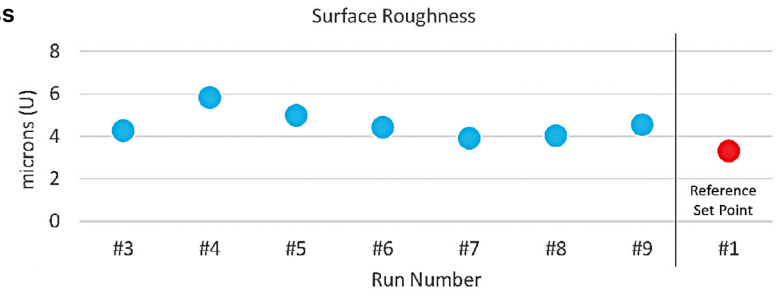
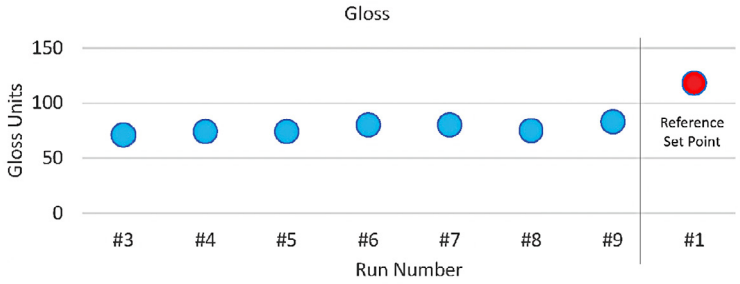


Figure 5: Gloss



Conclusions

Acceptable quality tablets were obtained across all parameters studied in the continuous coater. Tablets produced using the batch coater exhibited slightly higher gloss and lower surface roughness compared to the continuous process. It is important to consider the balance of elegance and productivity when comparing batch and continuous processes.

The results fully support feasibility of Opadry QX on a continuous coating line, and further work is required to examine the critical coating process parameters for the continuous coater to achieve even higher gloss levels, similar to those obtained in the batch coater.

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