

Continuous Coating Performance with Opadry® QX

Technical Bulletin

Quick and Flexible

In the area of continuous processing, focus has shifted from high throughput to process flexibility and improving manufacturing efficiency. Recent advances in continuous coating are enabling reduced coating cycle times with increased process flexibility (1). Additionally, regulatory agencies such as the U.S. Food and Drug Administration also see the benefits in modernizing manufacturing processes to reduce production interruptions and product failures (2).

Colorcon, as the leading innovator in ready formulated film coating systems, is working closely with the pharmaceutical industry to address the unique requirements for continuous and semi-continuous coating processes. The development of Opadry QX, quick and flexible film coating, provides the industry with a unique film coating formulation, suitable for use in continuous processes and scalable across traditional coating equipment with shorter application times. All this is achievable without sacrificing aesthetics of the finish, like smoothness or gloss.

Successfully tested in a variety of batch, continuous and semi-continuous coating machines, Opadry QX results in defect-free coated tablets with excellent appearance and color consistency. Colorcon continues to work with equipment manufacturers including Thomas Engineering, O'Hara Technologies, DRIAM, and GEA to progress a deeper understanding of the equipment and processes to provide high efficiency coating performance with excellent product quality. The process flexibility of Opadry QX is presented here, through case studies in three distinct types of continuous coating equipment.

High Throughput Continuous Coaters

The first continuous coaters provided increased throughput by modifying traditional side-vented pans and elongating the pan to a length of ten to fifteen feet (Figure 1); these pans typically process 500 – 1000 kg tablets per hour. With such high coating volumes, continuous coating was initially utilized in the manufacture of bulk dietary supplements and over-the-counter (OTC) consumer products. With lower production capacity demands for many prescription medicines, the scale of equipment is now being modified to range from 50 – 500 kg per hour. New mechanisms have also been developed to eliminate the start-up and shutdown inefficiencies previously associated with continuous processing (3).

In continuous operation, using the Thomas Flex CTC (Continuous Tablet Coater), Opadry QX was applied at 20% and 25% w/w solids with an average residence time of around 15 minutes to coat a 120 kg pan load of placebo tablets (standard round concave, 10 mm diameter). With an equivalent batch pan, the operation would take at least 40 minutes, using optimal process conditions. All tablets coated with Opadry QX were shown to be free from defects, maintaining excellent appearance at both 20 and 25% w/w solids levels (4).

In this study, the coating productivity was limited only by inability of the demonstration unit to feed tablets faster than 1080 kg/hr. In a commercial scale machine, higher throughput rates are achieved using higher coating solids levels of Opadry QX, at 30-35% w/w solution.



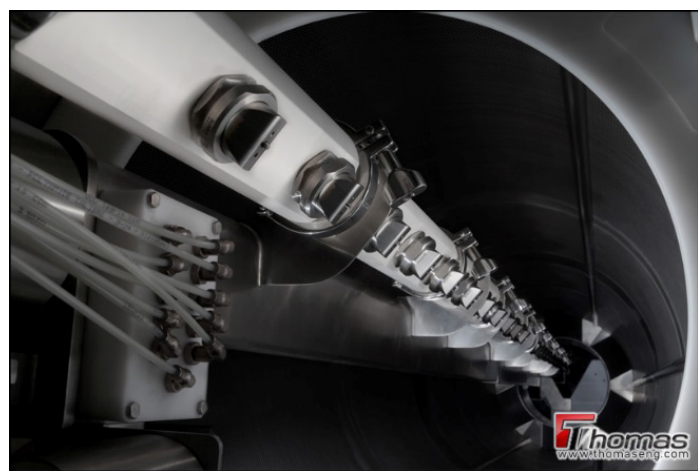


Figure 1. Thomas Engineering Flex CTC (Continuous Tablet Coater)

Multi-Chambered Continuous Cycled Coater

The DRIAM DRIACONTI-T pharma coating pan consists of an elongated coating pan, segmented along its length into seven individual pan chambers, allowing for optimal throughput between 50 and 120 kg/hr. Tablets progress between sections through a door opening in the pan divider wall, and the tablets are then forced into the next section. One key advantage of this design is the ability to run developmental coating parameters in a single-chamber in order to determine the optimal settings for production scale batches, enabling ease of scale-up.

In a case study, placebo tablets were coated with Opadry QX at 20, 25, 30 and 35% w/w solids, at a rate of 110-180 kg per hour; the resulting yield was defect-free final product with exceptional gloss and uniform color finish. Tablets coated with Opadry QX at the higher solids content (30 and 35% w/w) were virtually indistinguishable from those coated at a lower solids content (20 and 25%), demonstrating even greater process efficiency and superior appearance(5).

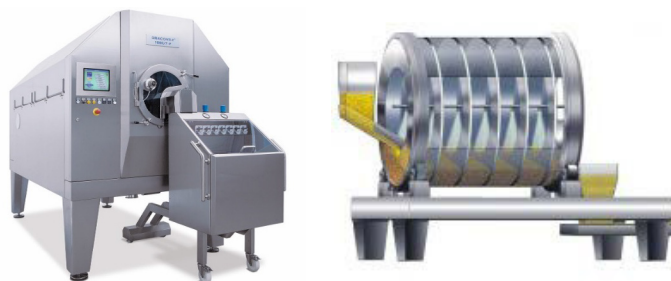


Figure 2. DRIAM DRIACONTI-T pharma (Continuous Cycled Coater)

Alternating Semi-Continuous Coating

GEA's ConsiGma™ coater is unlike traditional side-vented coating pans in both design and operation. The ConsiGma coater consists of two 18-inch diameter coating “wheels” which work in tandem to coat tablets semi-continuously; whilst one-unit coats, the second unit is filling. As the first unit discharges the 3 kg load of coated tablets, the next unit begins to coat; this repeats to enable “continuous cycle” coating.

Through more than 20 coating process trials using Opadry QX at 20-35% w/w solids, the residence times per 3 kg pan load averaged 5-10 minutes, potentially eliminating any bottlenecks in the continuous process train (blending, granulation, and tableting). All tablets were defect-free, uniformly coated and of good overall appearance (6).



Figure 2. GEA ConsiGma Coater

Summary

In processing with three unique continuous coating pan designs, Opadry QX showed advanced performance, resulting in color consistency and a defect-free, high gloss coating finish. Combining the capabilities of the novel equipment with the process flexibility of Opadry QX provides the opportunity to produce coated tablets at rates previously unimaginable.

Opadry QX, quick and flexible film coating system, is shown to be an innovative film coating formulation that can be prepared and applied quickly without sacrificing final coating appearance. These advantages make Opadry QX the ideal choice for continuous and semi-continuous processes.

With very low viscosity, Opadry QX provides significantly improved process efficiency compared to conventional hypromellose-based coatings. Formulation innovation enables dispersion concentrations from 20 to 35% w/w solids, resulting in application rates faster than any other coatings while delivering a perfect finish.

References

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