tablet coating

The role of high-solids coating systems in reducing process costs

Stuart C. Porter
International Specialty Products

This article discusses how high-solids coating systems can shorten processing times and reduce energy usage while meeting the requirements of today's pharmaceutical products. High-solids coatings can also facilitate adoption of continuous coating.

Traditional aqueous coating formulations limited sprayable solids to about 5 to 10 percent by weight (w/w) for clear coating systems and about 12 to 15 percent w/w for pigmented systems. For the last 20 years, however, coating systems with solids content in the range of 15 to

20 percent w/w have been available. Today, coating systems are available with a sprayable solids content of 20 to 30 percent w/w, due in large part to incorporation of polymers such as poly(vinyl alcohol) (PVA), copovidone, and PVA-polyethylene glycol copolymer.

Clearly, the use of coating formulations with sprayable solids content in excess of 20 percent w/w can significantly reduce coating process times, because doing so reduces the amount of coating suspension necessary to achieve the required coating weight gain. Many of these specialized coating systems also confer other benefits, including

- Lower coating solution/suspension properties (viscosity);
- Better film adhesion to tablet substrates;
- Better barrier properties (to environmental moisture and/or oxygen);
- Better film physical properties, such as greater film strength and/or flexibility; and
- More elegant coating appearance.

This article summarizes how adopting high-solids coatings can reduce costs. Lower costs typically stem from

- Shorter processing times;
- Implementation of new processing technologies (such as continuous film coating);
- Reduction in energy usage;
- Further reduction in use of organic solvents for processes/products where difficulties with implementing aqueous processes persist (primarily because of inadequate drying characteristics); and
- Better product stability.

Shorter processing times

As the data in Figure 1 show, today's new breed of high-solids coating systems have viscosities that are much lower than before. The lower viscosities permit application of coating suspensions in more concentrated form, typically in excess of 20 percent w/w solids, and often as high as 25 to 30 percent w/w solids. The higher solids content, in turn, offers an opportunity to reduce coating process times significantly, as the data in Table 1 demonstrate.

While the ability to increase productivity—and thus reduce cost—is clearly evident, that advantage must be tempered by the need to apply the coating uniformly. Uniform application can be greatly influenced by the length of the coating process, because that timeframe has a direct bearing on how many times the tablets (statistically) are presented to the spray. Thus, employing coating systems with high solids content can pose a serious challenge to uniform application.

To reduce coating time and achieve acceptable coating uniformity, manufacturers of high-solids coating systems often recommend that the sprayable solids content of their coating systems be limited to about 20 percent w/w, unless other factors—such as lack of drying capacity in the process or API sensitivity to moisture—prevail. In those cases, higher solids content would be warranted because it would reduce the amount of water to be evaporated, thus lowering the burden on the less-than-adequate drying conditions.

The potential of continuous coating

Manufacturers have practiced continuous coating for about 15 years, albeit in very select applications, such as coating large volumes of OTC pharmaceutical and nutraceutical products. Mancoff [1] was the first to provide insight into this new processing technology for coating pharmaceutical tablets, while Porter [2] provided a more recent review of the potential benefits of continuous coating.

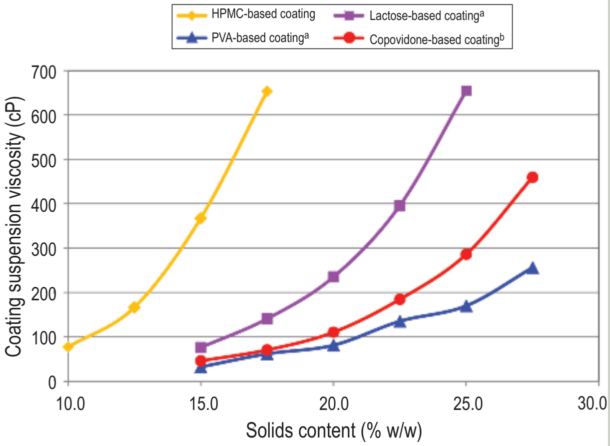
While continuous coaters have typically been restricted to specialized coating applications, the benefits of the process are becoming more widely appreciated, especially as smaller continuous coaters are introduced. (The smaller units suit the needs of more pharmaceutical companies.) The growing appeal of continuous coating processes has occurred in no small part because 1) equipment suppliers have resolved some of the earlier start-up and shut-down issues associated with continuous processing, and 2) it's possible to operate continuous coaters in batch mode.

Yet one big challenge of continuous coating has remained: The short residence time of tablets within the coating pan (typically 15 to 25 minutes). This short period imposes a significant burden on our ability to deposit the requisite amount of coating material. High-solids coating systems resolve this problem and make available the major benefits of continuous coating, including

- Rapid throughput (with shorter coating process times);
- Less exposure to harsh processing conditions;
- More uniform distribution of the coating material; and
- Less coating material required.

FIGURE 1

Comparative viscocity profiles for various types of aqueous coating systems



Notes:
[a] = Opadry II from Colorcon, West Point, PA
[b] = Advantia Preferred HS from ISP, Wayne, NJ

Each of these benefits can reduce costs, as the summary in Table 2 shows.

Initially, the ability of continuous coaters to operate in batch mode might seem to be a retrograde step, but it really does represent an important advance in coating process technology. For example, as shown by Cunningham et al. [3], a continuous coater with capacity to coat 250 kilograms of tablets in batch mode can achieve uniform, complete color development in less than 15 minutes when applying a coating suspension with a solids content of 20 percent w/w. A more traditional batch coater of similar capacity would require about 90 minutes to achieve

Table 1

Examples of potential process time savings from using a high-solids coating system

Process parameter	Parameter settings: HPMC-based coating system at 15% w/w solids	Copovidone-based coating system at 20% w/w solids[a]	Copovidone-based coating system at 25% w/w solids[a]
Spray gun type (number)	Manesty Opti Coat (3)	Manesty Opti Coat (3)	Manesty Opti Coat (3)
Pan loading (kg)	170	170	170
Gun-to-bed distance (cm)	28	28	28
Pan speed (rpm)	5.0	7.0	6.0
Process-air volume (m^3/h^{-1})	2,200	2,300	2,300
Process-air volume (cfm)	1,300	1,350	1,350
Inlet-air dewpoint (°C)	10 - 13	10 - 13	10 - 13
Inlet-air temperature (°C)	60	65	65
Tablet bed temperature (°C)	39	40	42
Exhaust-air temperature (°C)	45	49	50
Atomizing-air pressure (bar)	2.5	2.5	2.5
Pattern-air pressure (bar)	2.0	3.5	3.5
Spray rate (grams per min^{-1})	315	388	380
Amount of coating suspension applied (kg)	36.2	31.4	25.2
Coating process time (min)	115	81	66
Process time savings (%)	-	30	43

Note: [a] = Advantia Preferred HS from ISP, Wayne, NJ

Table 2

Opportunities to reduce costs in film coating: Potential impact of continuous coating process

Parameters	Batch coaters: Pan with 150-kg nominal fill capacity	Batch coaters: Pan with 150-kg nominal fill capacity	Batch coaters: Pan with 150-kg nominal fill capacity	FC C1200 continuous coater (250-kg nominal fill capacity in non-continuous mode)
Coating capacity to achieve a 3% weight gain (kg/h^{-1})	92	140	188	1,200 (continuous mode)
Coating solids (% w/w)	17.1			
Bed depth (cm)	34.3	49.5	57.2	15.2
Coating capacity for one shift (kg/year)	184,000	280,000	377,000	2,400,000
Number of coating machines required to match capacity of continuous coating process	13	8.6	6.4	1
Comparative cost (capital and expected operating expenses)	$13.7 million	$10.0 million	$8.0 million	$3.1 million

Note: Data kindly provided by O'Hara Technologies, Richmond Hill, ON, Canada the same result. This reduction in processing time reduces costs without (potentially) compromising coating uniformity, at least when uniformity is assessed visually, which is the usual method employed for products coated with a colored immediate-release (IR) film coating.

Combining high-solids coating systems with low-temperature coating processes

During the era when film coatings employing organic solvents dominated, it was commonly recognized that processing temperatures (more specifically product temperatures) were much lower than those typical of today's aqueous processes. The primary reason for this was, and still is, the greater volatility of organic solvents, which obviates the need for coating at high temperatures.

The current preference for aqueous coating systems means processing temperatures are much higher because the coating process must 1) effectively evaporate a solvent that has a higher latent heat of vaporization, and 2) ensure that ineffective solvent evaporation does not compromise product stability.

It is not, therefore, uncommon to see companies retain organic solvent-based coating systems in situations where either the API is sensitive to heat, or where the drying capability of the coating process is insufficient to ensure that an aqueous coating system can be effectively dried. The use of high-solids aqueous coating systems potentially overcomes these limitations, allowing aqueous coatings to be used in almost all operations that apply an IR film coating.

The examples in Figure 2 illustrate how a high-solids coating system based on copovidone, when applied at 20 percent w/w solids, can potentially be used to design a coating process that operates at temperatures substantially lower than those typical of an aqueous process. What is also evident, as the examples in Figure 3 indicate, is that when attempting to achieve really low product temperatures, the moisture content of the processing air becomes a more critical factor. The ability of the processing air to evaporate water is directly related to the moisture-carrying capacity of that process air. Thus, once heat (at low temperatures) is eliminated as a key factor, the moisture-carrying capacity of the processing air is much more directly affected by both the existing moisture content in that air and the amount of water that has to be evaporated. In this example, where the solids content of the coating system was set at 20 percent w/w, process thermodynamics could be further improved by increasing the solids content to, for example, 25 percent w/w. This improvement is possible because the higher solids content reduces the spray application rate.

The data in Table 3 exemplify how a high-solids coating system can be used to coat a product containing a heat-sensitive API (atorvastatin). In this case, it was necessary to replace an organic solvent-based coating system with an aqueous one without exposing the product to substantially higher processing temperatures.

Despite the good results of that application, successful low-temperature aqueous film-coating processes remain challenging because process temperatures greatly affect the evaporative capacity of the process. Restricting the amount of water that needs evaporation is one approach. Another approach, and just as important, is to increase the evaporative capacity of the process air stream by keeping the moisture content of the inlet air as low as possible (low dew-point). The examples in figures 2 and 3 illustrate the importance of both approaches.

In summary, the application of high-solids coatings enables the use of lower-than-typical coating process

Figure 2

Examples of coated tablets and the process conditions during application of a coating system containing 20 percent w/w solids

a. Typical process conditions
Inlet-air temperature = 55°C
Product temperature = 38°C
Exhaust-air temperature = 41°C
Process-air dew-point = 0.3°C

b. Intermediate process conditions
Inlet-air temperature = 41°C
Product temperature = 28°C
Exhaust-air temperature = 32°C
Process-air dew-point = 0.3°C

c. Challenging process conditions
Inlet-air temperature = 37°C
Product temperature = 24°C
Exhaust-air temperature = 29°C
Process-air dew-point = 8.5°C

temperatures, thus facilitating the elimination of organic solvents (itself a potential source of cost savings) and reducing the overall energy costs associated with the process.

Opportunities to improve product stability

Improving product stability using high-solids coating systems relates to several factors, including

- Potential reduction in processing temperatures, thereby creating a less stressful process, especially for APIs that may be heat sensitive (as addressed above);
- Reduction in the amount of solvent (water) that must be evaporated, which also reduces the API's exposure to a solvent implicated in many stability problems; and
- Availability of many polymers used in high-solids coating systems that possess barrier properties that can restrict exposure to environmental gases, such as water vapor and oxygen [4, 5].

The photos in Figure 4 show how the application of a high-solids coating system can improve the stability of a nutraceutical product, even when that coating system does not use a polymer commonly considered to act as a moisture-barrier. In this example, stability likely improved because the application of a high-solids coating limited tablet exposure to moisture during film coating.

Better product stability not only improves product shelf-life, but also produces a related cost benefit. This can happen when the coating formulation possesses appropriate barrier properties that improve product protection enough that less expensive packaging materials can be used.

FIGURE 3

Impact of process-air dew-point on coated tablet quality when applying a high-solids coating system at 20 percent w/w solids under low-temperature processing conditions

a. Elevated dew-point condition

Inlet-air temperature = 28°C
Product temperature = 18°C
Exhaust-air temperature = 22°C
Process-air dew-point = 9.2°C

b. Low dew-point condition

Inlet-air temperature = 27°C
Product temperature = 20°C
Exhaust-air temperature = 21°C
Process-air dew-point = 0.2°C

Summary

High-solids coating systems provide a plethora of potential benefits, not least of which are opportunities for reducing manufacturing costs and limiting exposure of the product to stressful process conditions, which include mechanical agitation (tumbling), high temperature, and high humidity. These benefits alone warrant consideration of high-solids coating systems, but the case becomes even stronger when the possibility of implementing newer processing technologies is factored in. It is more favorable yet when those technologies help meet the challenges imposed by the FDA's QbD initiatives. *T&C*

References

1. Mancoff, W.O., "Film coating compressed tablets in a continuous process." Pharm. Technol., 22:12-18 (1998).

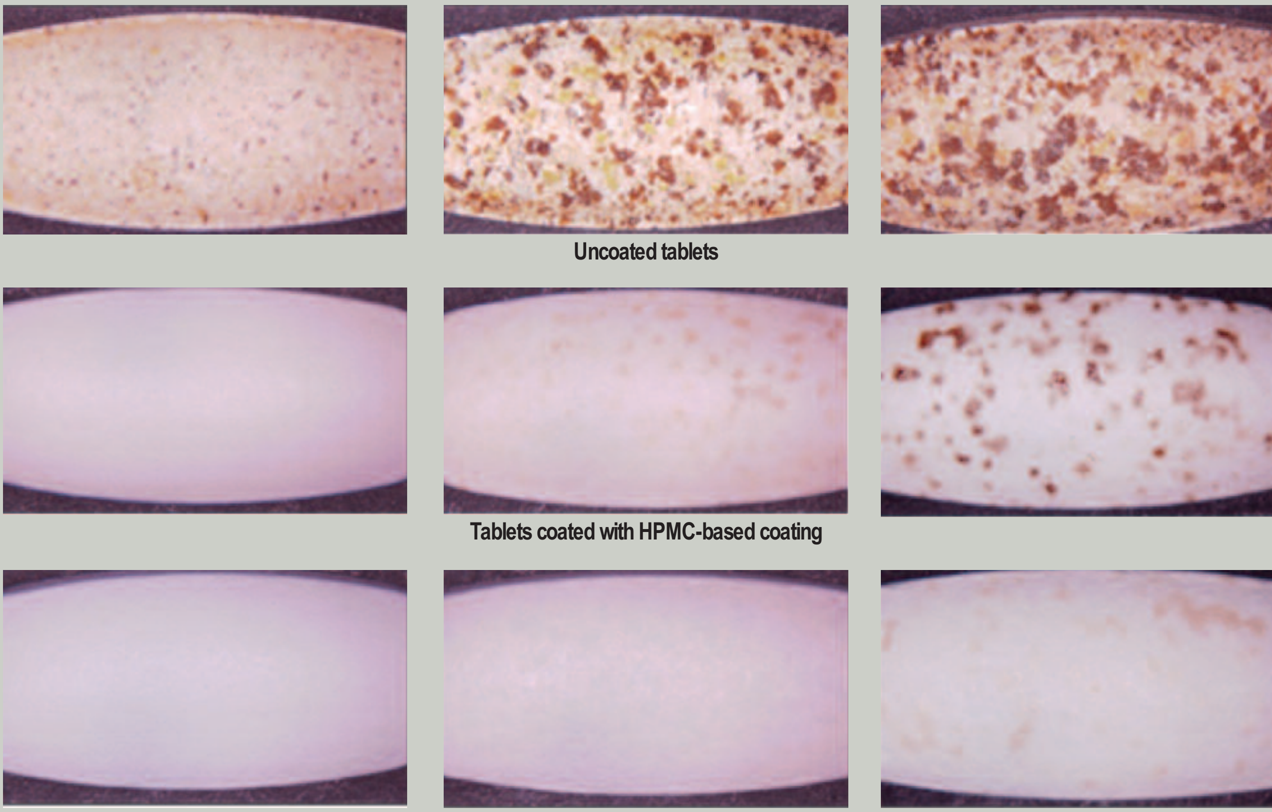
TABLE 3

Process settings used to coat atorvastatin tablets—in a lab-scale coating process—with an aqueous coating system applied at 25 percent w/w solids

Process parameter	Process set-point
Pan loading (grams)	600
Pan speed (rpm)	15
Inlet-air volume (cfm) [m^3h^{-1}]	30 [50]
Inlet-air temperature (°C)	60
Product temperature (°C)	33
Exhaust-air temperature (°C)	35
Process-air dew-point (°C)	12.9
Spray rate (grams per min^{-1})	4.7
Atomizing-air pressure (bar)	2.5

Figure 4

Visual characteristics of multi-vitamin tablets stored in sealed HDPE bottles for up to 3 months at 40°C/75 percent RH



Notes:
[a] = Advantia Preferred HS from ISP, Wayne, NJ

2. Porter, S.C., "Continuous film coating processes: A review." *Tablets & Capsules*, 4: 26-29 (2007).

3. Cunningham, C., Hansell, J., Nuneviller III, F., and Rajabi-Siahboomi, A.R., "Evaluation of recent advances in continuous film coating processes." Drug Dev. & Ind. Pharm., 36(2): 218-226 (2010).

4. Cech, T. and Mistry, M., "Defining the ideal properties of a moisture protective, instant release film coating." Pharm. Tech. Europe, 21(10): (2009).

5. "Correlation of free salicylic acid content to the water vapor transmission properties of aqueous film coating systems." Opadry amb/Opadry II application data bulletin (2009), Colorcon.

Stuart C. Porter, Ph.D., is senior director, global pharma applications R&D at International Specialty Products, 1361 Alps Road, Wayne, NJ 07470. Tel. 973 628 3372. E-mail: sporter@ispcorp.com. He is also member of Tablets & Capsules' *Technical Advisory Board.*