The Effect of Coating Process Conditions and Coating Formula Type on the Quantity and Location of Water in Film Coated Tablets

OBJECTIVES

- To examine the effects of coating process conditions and film coating formulation type on tablet moisture gain.
- To determine the amount and location of water in film coated tablets.

BACKGROUND

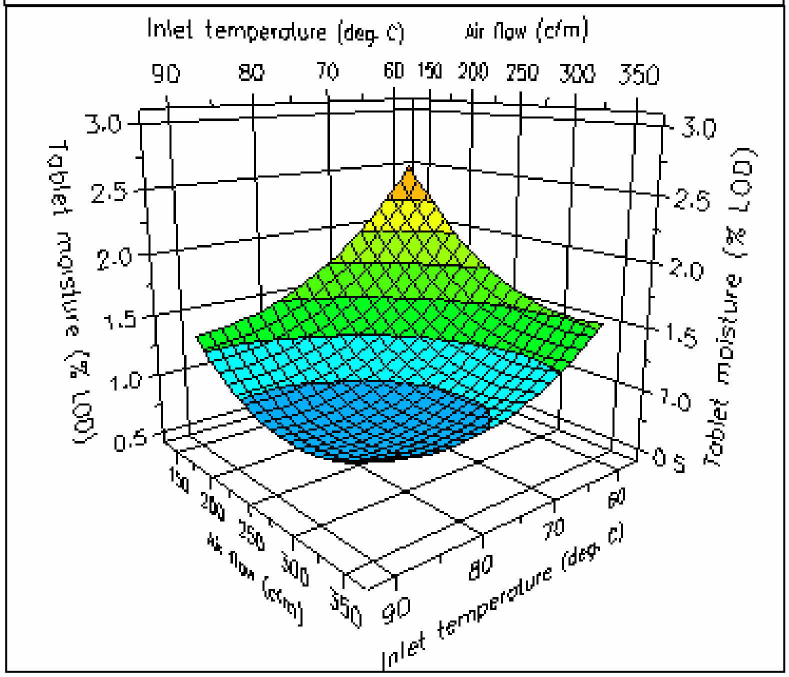
Due to regulatory and safety considerations, water has become the medium of choice for coating pharmaceutical products. Since many solid dosage forms are moisture sensitive, it is imperative that coating process conditions be defined that will result in successful water-based coating without increasing the water content of cores or its potentially deleterious effects during the coating process.

Previous studies have shown that air flow and inlet temperature can significantly influence the final moisture content of a coated product.[1] Under some conditions, it was actually possible to reduce the moisture content of the uncoated core (initially 1.4%).

Figure 1. Moisture Content

Tablet Moisture Response Surface

Spray Rate = 35, Solids Concentration = 20



This new study focused on the effects of pre-drying the tablet bed as well as varying the bed temperature.

METHODOLOGY

Three different film coating formulas, Opadry®, complete film coating system (03F18435), Opadry® II, high performance film coating system (85G18490) and Opadry amb, aqueous moisture barrier, film coating system, (80W68912) were coated onto tablets using both “dry” and “wet” coating process conditions. Standard round, biconvex 11mm placebos were used for the cores.

An O’Hara Labcoat I with a 12” pan insert and one VAU Spraying System spray gun were used along with the following standard process conditions:

- Inlet air flow: 125 cfm
- Atomizing air pressure: 25 psi
- Pattern air pressure: 20 psi
- Pan rotation speed: 18 rpm

The “dry” process conditions included pre-heating the tablets at 50°C for 15 minutes prior to coating, and then maintaining a bed temperature of 47°C or greater during coating. The “wet” process conditions included initiating coating once the bed temperature reached 40°C and maintaining that bed temperature during coating.

Uncoated cores and coated tablets were pulverized and analyzed for water content by Karl Fischer (Direct) titration method. A single composite sample from six tablets was used for the analysis of each batch.

The relative water concentration throughout the tablets was determined by a SapphireTM NIR Chemical Imaging System. The spectral band for water (1930 nm) was identified and used to measure moisture within each tablet. Using the Karl Fischer data from various samples, Partial Least Squares (PLS) Modeling was applied to the data set allowing the spectra to be assigned specific moisture concentration levels. All measurements were made in diffuse reflection mode.

Figure 2. NIR Chemical Imaging: Samples

Three tablets from each formula type and each set of conditions were analyzed.

- “Cross section” presentation
- “Tablet face” presentation

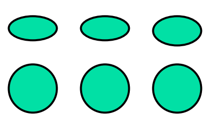


Table 1. NIR Chemical Imaging: Data Collection Parameters

Spectral Range	1300-2400 nm, 10 nm increment
Collection Time	~4 min/image
Background Reference	White ceramic
Dark Reference	Stainless steel mirror
Spatial Resolution	40µm/pixel (square pixels)
Format	320 x 256 (81,920) pixels
Field of View	12.8 mm x 10.2 mm

Source-illuminator polarizers were used to eliminate possible specular-reflectance.

TABLET MOISTURE RESULTS

The tablet sample results from Karl Fischer moisture analysis indicate that there was less moisture in the tablets coated with the “dry” process conditions than there was in the tablets coated with the “wet” process conditions. However, the highest level of moisture was in the uncoated tablets.

Table 2. Karl Fischer – % Moisture of Samples

Uncoated Tablet	Opadry		Opadry II		Opadry amb	
	“dry”	“wet”	“dry”	“wet”	“dry”	“wet”
5.40%	4.29%	5.36%	4.27%	5.00%	3.94%	4.62%
(difference)	(-1.11)	(-0.04)	(-1.13)	(-0.40)	(-1.46)	(-0.78)

These results indicate that both the “dry” and “wet” coating process conditions enabled sufficient water removal capacity to result in a net reduction of the moisture content in the cores.

The “dry” process conditions affected the tablet moisture level by actually “drying out” the tablets. The “dry” process involved pre-heating the tablets at 50°C for 15 minutes while jogging the pan. This is ample time for the heated air flow to evaporate some inherent tablet moisture.

The “wet” process conditions involved immediately spraying once the tablet bed reached 40°C and maintaining that same temperature. This still involves a short amount of time at the beginning of the run when the heated air flow can evaporate some inherent tablet moisture. Although it is a much lower amount than with the “dry” conditions.

NIR Chemical Imaging - % Moisture and Location

Table 3. Tablet Sample Grid for Images

Uncoated (1 tablet)	Opadry “dry” (3 tablets)	Opadry “wet” (3 tablets)
Uncoated (1 tablet)	Opadry amb “dry” (3 tablets)	Opadry amb “wet” (3 tablets)
Uncoated (1 tablet)	Opadry II “dry” (3 tablets)	Opadry II “wet” (3 tablets)

Figure 2. Tablet Sample Cross Sections

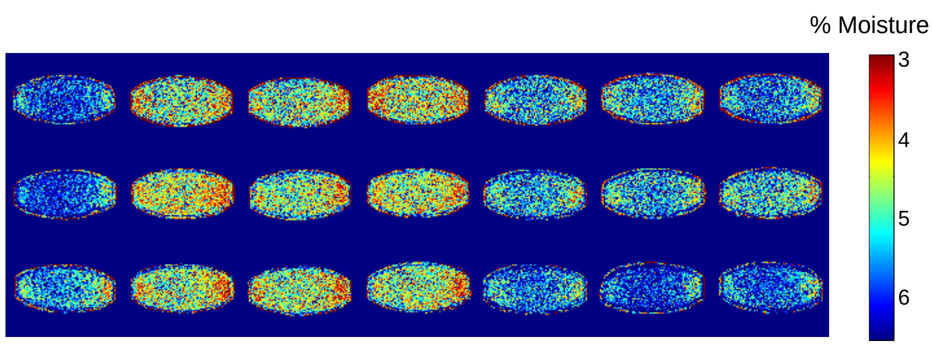
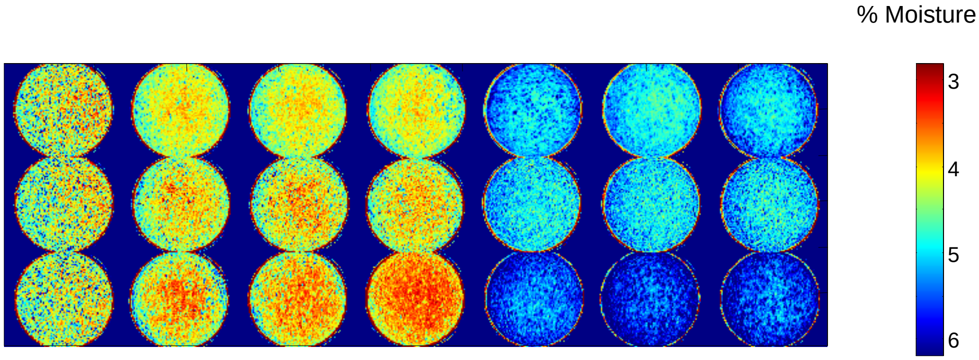


Figure 3. Tablet Faces



The NIR Chemical Imaging results also show a distinct difference in the moisture level of the tablets coated with “wet” process conditions vs. the tablets coated with “dry” process conditions. The distribution of water appears to be fairly uniform throughout all tablets. There is slightly less moisture around the edges of the tablets, which may be due to higher density and therefore lower porosity in this region. There were no significant differences between water distribution in cores coated with the different film coatings.

CONCLUSIONS

- Both the “dry” and “wet” coating process conditions of this experiment allowed tablets to be coated while maintaining or decreasing the moisture content.
- The water in uncoated and coated tablets is, for the most part, uniformly distributed.
- The coating of water-sensitive cores using an aqueous film coating process can result in coated tablets with no increase and potentially a decrease in moisture content, depending on the coating process conditions used.

REFERENCES

1. Cunningham, C., Farrell, T. & Quiroga, A. (2005) SAFyBI Poster Presentation, Buenos Aires, AR.

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