OPADRY® *II*

Application Data

High Performance Film Coating System

Coating Moisture-Sensitive Products

OBJECTIVES

To determine the coating process conditions which influence moisture uptake by cores.

BACKGROUND

Because of regulatory and safety considerations, there is a global trend to switch from organic to aqueous solvents in film coating processes. The need to protect moisture-sensitive products during the coating process is equally important. Therefore, it is imperative to develop film coating formulas and processes that minimize the ingress of water and its deleterious effects in film-coated dosage forms. This work identified the important coating process variables which influence water content in film coated tablets.

METHODOLOGY

Film Coating & Equipment

Coating: Opadry® II, high performance film coating system, 85F Orange

Coating Pan: O'Hara Labcoat II fitted with a 24" pan used for all coating trials

Spray Guns: 2 Spraying Systems VAU 4078 with 113293-60 air caps

Pump: Masterflex Model 7523-30 with 96410-15 silicone tubing

Multivitamin Tablet - Uncoated

Shape: Oblong

Weight: 1008.7 mg

Breaking force: 13.4 kp

Thickness: 5.92 mm

Length: 19.21 mm

Moisture Content: 1.4%

(Weight, Breaking force, Thickness: n = 20)

Table 1. Experimental Variables

Variable Name	Units	Range
Inlet Temperature	°C	60 - 90
Spray Rate	g/min	35 - 70
Solids Concentration	%	15 - 25
Air Flow	ft^3/min (cfm) m^3/hr	150 - 350 255 - 595

Table 2. Experimental Constants

Variable Name	Units	Level
Atomization pressure	psi/bar	40/2.7
Pattern pressure	psi/bar	40/2.7
Pan speed	rpm	14
Pan charge	kg	20
Guns	number	2

Response Variables

Qualitative – Visual Assessment: Cracking, peeling, edge chipping, other defects

Quantitative: Moisture change in the core, surface roughness, gloss

Moisture Content

The starting moisture content of the vitamin tablet was 1.4%.

Tablets were sampled immediately upon the completion of each trial. The tablets were gently crushed and tested for % loss-on-drying using an Ohaus MB 200 automated moisture balance (115°C for 35 min).

Over the range of experiments, moisture ranged from 0.6% to 2.7%.

RESULTS

Table 3. Experimental Conditions

Run No.	Inlet temperature (deg. C)	Spray rate (g/min)	% Solids	Air flow (cfm)
1	90.0	75	25.0	150
2	67.5	65	22.5	200
3	90.0	35	15.0	150
4	90.0	55	25.0	350
5	75.0	35	25.0	150
6	60.0	75	15.0	150
7	82.5	45	22.5	300
8	75.0	75	25.0	350
9	60.0	55	25.0	150
10	60.0	35	25.0	350
11	67.5	65	22.5	300
12	90.0	35	25.0	250
13	82.5	45	22.5	200
14	67.5	45	17.5	300
15	60.0	35	25.0	350
16	75.0	55	15.0	250
17	82.5	65	17.5	200
18	75.0	55	20.0	250
19	60.0	35	15.0	150
20	90.0	75	15.0	350
21	90.0	75	25.0	150
22	82.5	65	22.5	300
23	67.5	45	22.5	200
24	75.0	55	20.0	250
25	60.0	75	25.0	250
26	90.0	35	15.0	350
27	60.0	75	15.0	350

Figure 1. Qualitative Results (Trials 6, 9 &19)

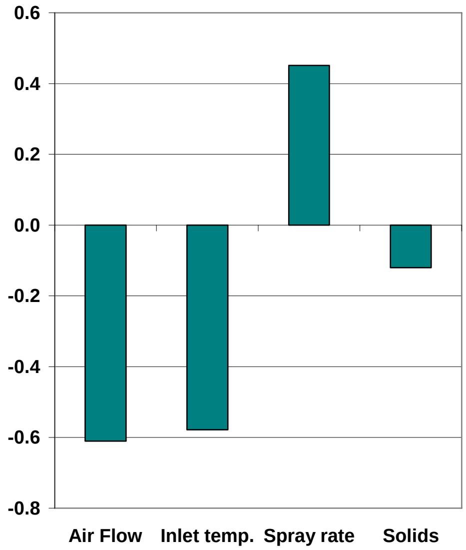
Figure 2. Qualitative Results (Trial 26)

Highest airflow (350 cfm/595 m^3/hr)

Highest inlet air temperature (90°C)

Still the best appearance

Figure 3. Moisture Content – Regression Analysis



Regression

R Square: 0.9874

Adj. R Square: 0.9748

Error %: 1.00

Error Variante: 0.002

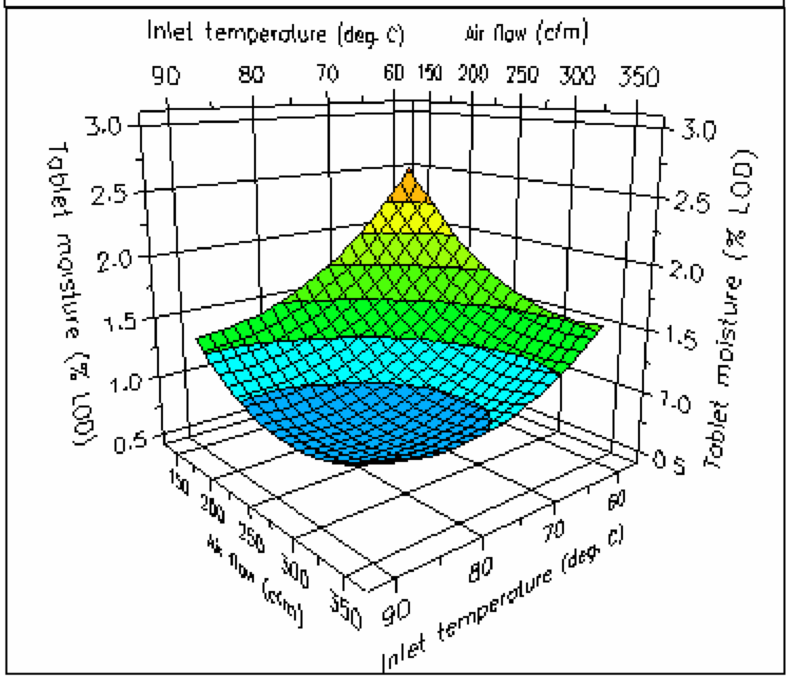
Error Std. Dev.(±): 0.041

95% Confidence Limits(±): 0.130

Figure 4. Moisture Content – Response Surface

Tablet Moisture Response Surface

Spray Rate = 35, Solids Concentration = 20



CONCLUSIONS:

1. The water content in cores may actually be reduced during the film coating process.
2. Moisture content decreases with increasing inlet temperature and increasing air flow.
3. Moisture content increases with increasing spray rate.
4. Film coated tablets with excellent appearance and low moisture content may be produced by carefully selecting coating process parameters.

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