COMPARISON OF COATING EFFICIENCY BETWEEN A VECTOR HICOATER AND A MANESTY ACCELA COTA

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ABSTRACT

The coating efficiency of a Vector HiCoater was compared to that of a Manesty Accela Studies were conducted in 24", Cota. and 67" HiCoaters, and in 24" and 60" Accela The coating system was composed of yellow iron oxide, titanium dioxide, polyethylene glycol, and hydroxypropyl methylcellulose. Timed serial tablet samples were examined using a tri-stimulus The 67" HiCoater applied 300 mg colorimeter. of coating solution per kilogram of tablets

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(480 kg pan load) in 209 minutes, whereas the 60" Accela Cota applied a similar amount of material to a 360 kg pan load in 165 minutes. The Hunter Lab values at these times were 58.7 ± 0.4 , 10.7 ± 0.5 , and 29.8 ± 0.3 for the HiCoater, and 59.9 \pm 0.2, 10.5 \pm 0.4, and 30.0 + 0.2 for the Accela Cota for L, a, and b respectively. Although the run time was 44 minutes longer with the HiCoater, the batch size was increased 33%.

INTRODUCTION

The advent of film coating (1) has been accompanied by a rapid increase in the available equipment options used to apply film forming materials. Considering the international scope of many pharmaceutical organizations, the preferences in equipment can be quite varied among development, scale-up, and production functions; or among production sites. Thus, this situation requires an understanding of the coating efficiencies among types and sizes of coating equipment.

The purpose of this investigation was to more clearly define the practical coating efficiencies of the Vector HiCoater and the Manesty Accela Cota. Scale-up data in both equipment lines has been generated.

MATERIALS AND METHODS

The tablets used in all trials except the 60" Accela Cota run were composed of 92% Lactose, USP, Hydrous (Foremost Fast-Flo, Wisconsin Dairies, Baraboo, WI), 7% Microcrystalline Cellulose, NF (Avicel PH102, F.M.C., Corp., Philadelphia, PA), and 1% Magnesium Stearate, NF (McKeeson, Hummelstown, The materials were blended in a suitably sized PA). mixer and then compressed to an average weight of 403 mg and a hardness of greater than 11 kp. Tablets used in the 60" Accela Cota run were of similar composition but prepared by a wet granulation method.

The coating formula was a dispersion of hydroxypropyl methylcellulose (6 cps, Shin-Etsu Chemical Co., Ltd., Tokyo, Japan), polyethylene glycol, and yellow Speedpaste (D. F. Anstead, Ltd., Billeriray, UK), or Chroma-Kote (Crompton and Knowles



TABLE 1: Thomas Engineering/Manesty Accela Cotas and Vector HiCoaters Sizes and Capacities

<u>Pan</u>	<u>Model</u>	Tablet Load (kg)
Accela Cota	24"	10
Accela Cota	60"	360
HiCoater	24"; HCT- 60	20
HiCoater	52"; HCT-130	150
HiCoater	67"; HCT-170	480

Corp., Fairlawn, NJ). The Speedpaste and Chroma-Kote contained titanium dioxide, yellow ferrous oxide, hydroxypropyl methylcellulose, and SDA 3A alcohol. minimum of 300 g of coating dispersion was sprayed per kilogram of tablets.

The coating pans used for the trials included in this study are given in Table 1. The respective U.S. suppliers for the Accela Cota and HiCoater systems are Thomas Engineering, Inc., Hoffman Estates, IL, and Vector Corporation, Marion, IA. The 60" Accela Cota trial was carried out in the United Kingdom, with a unit supplied by Manesty, Ltd; Liverpool. The larger pan load in a 24" HiCoater as compared to the 24" Accela Cota is due to a greater pan depth.

In general, equipment set-up was held constant. For example, 2.5 mm air caps and 1.2 mm nozzles were Minor differences in used in all HiCoater runs. equipment, such as heating type (electric versus steam), did exist. Table 2 contains information concerning spray rate, pan speed, and number of spray For the most part, the inlet guns used in each run. temperature was held at about 80°C and the outlet temperature at about 50°C. Preconditioned air sources were not used.

The efficiency of the coating process was evaluated from tri-stimulus colorimeter data. type of equipment has been previously used to measure the opacity of tablet film coatings, and for color matching between film coating materials. (2,3) are several coordinate systems available, including the XYZ, CIE Lab, and the Hunter Lab Systems. Hunter Lab system was used in this study. The L coordinate characterizes the variation from black to



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TABLE 2: Set-up and Operating Parameters for Coating Runs

		Number	Pan	Average Spray
	Load	of Spray	Speed	Rate
	<u>(kg)</u>	<u>Guns</u>	(rpm)	(g/min)
24" Accela Cota	10	1	12	33.3
60" Accela Cota	360	3	4-4.5	654.0
24" HiCoater	20	2	8	47.0
52" HiCoater	150	3	6	209.0
67" HiCoater				
Trial #1	480	4	4	689.0
Trial #2 ^(a)	480	4	4	692.0

(a) Crompton and Knowles Corporation Chroma-Kote; all other trials with D. F. Anstead, Ltd. Speedpaste

white and varies in numerical value from 0 to 100. The a coordinate describes the red to green component and varies from +50 to -50, and b describes blue to yellow and varies from -50 to +50.

Color measurements were made with a Model 05 Colorquard Colorimeter (Pacific Scientific, Chevy Chase, MD), through a 9 mm opening for all trials except the 60" Accela Cota trial. In that trial a Hunter Lab, D25A-9 unit equipped with a 10 mm aperture was used.

As each coating run proceeded, timed serial samples of at least 20 tablets were removed from the Colorimeter readings were taken and the mean values and standard deviations (S.D.) were calculated for the L, a, and b coordinates.

RESULTS AND DISCUSSIONS

The major difference between the Accela Cota and HiCoater equipment lines is the location of perforations in the coating pan. The HiCoater (Figure 1a) has four equally spaced perforated exhaust air panels, whereas the Accela Cota (Figure 1b) is perforated around its entire circumference. results in a difference in the air flow through each



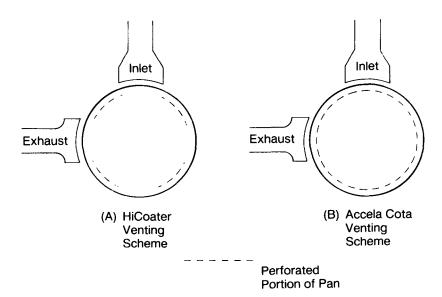


Figure 1:

- (a) Schematic of HiCoater ventilation system
- (b) Schematic of Accela Cota ventilation system

Set-up in the HiCoater and Accela Cota TABLE 3:

Pan	Scaling from → to (pan diameter)	Increase in Tablet Load (%)	Increase in Spray Rate (%)
HiCoater	24" → 52"	85	72
HiCoater	52" → 6 7 "	45	45
HiCoater			
Trial #1	24" → 67"	96	92
Trial #2 ^(a)) 24" → 67"	96	93
Accela Cota	24" → 60"	97	92

Crompton an Knowles Corporation Chroma-Kote; all other trials with D. F. Anstead, Ltd. Speedpaste.



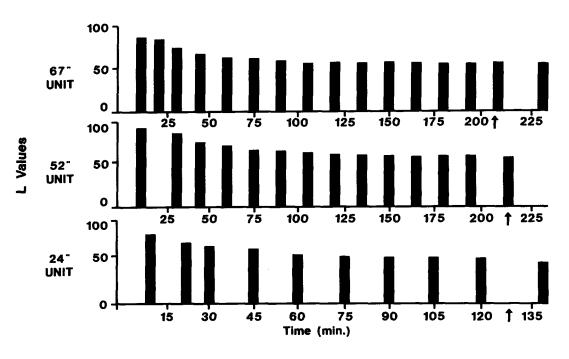


Figure 2:

Hunter L values vs time for the 67", 52", and 24" HiCoater units. The arrow indicates time point where 300 g of coating dispersion per kilogram of tablets was applied.

type of pan and, therefore, a difference in the heat transfer within each system.

A fairly linear $(r^2 = 0.985)$ increase in pan speed, of 0.9 rpm, was found with each 10" increase in pan diameter for the HiCoater (Table 2). speed was decreased from 12 rpm to 4-4.5 rpm in scaling up from the 24" to 60" Accela Cota.

Table 3 contains information on the percentage increase in tablet load and spray rate among the different sized coating pans. It appears that in this



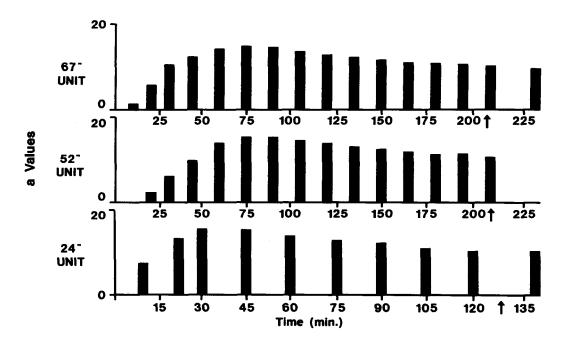


Figure 3:

Hunter a values vs time for the 67", 52", and 24" HiCoater units. The arrow indicates time point where 300 g of coating dispersion per kilogram of tablets was applied.

study, tablet load served as an accurate reference to the observed increase in mean spray rate required to efficiently and aesthetically apply a film coat to the placebo tablets.

Figures 2-7 detail the Hunter Lab values throughout the various coating trials. The time domains have been adjusted so that the duration of a group of trials occupy a similar length of abscissa. Figures 2-4 correspond to the HiCoater trials while Figures 5-7 refer to the Accela Cota runs. HiCoaters, 1 minute in the 24" pan gave similar Hunter Lab values as 1.67 minutes in the 52" and 67" units.



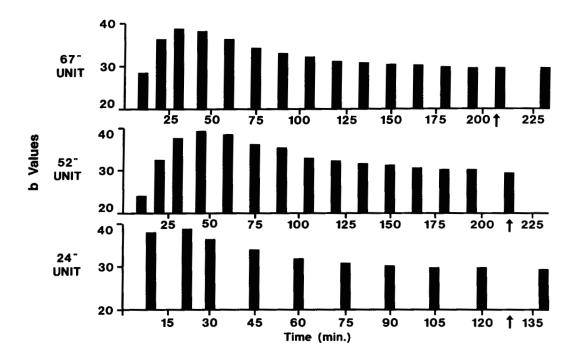


Figure 4:

Hunter b values vs time for the 67", 52", and 24" HiCoater units. The arrow indicates time point where 300 g of coating dispersion per kilogram of tablets was applied.

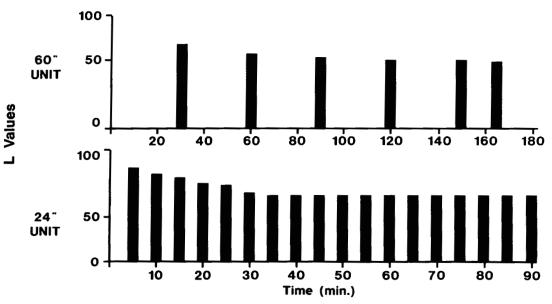


Figure 5:

Hunter L values vs time for the 60" and 24" Accela Cota units.



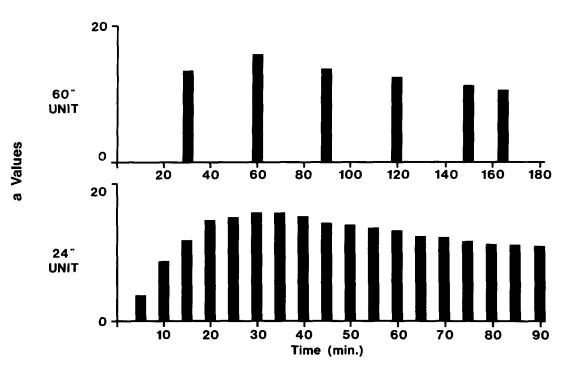


Figure 6:

Hunter a values vs time for the 60" and 24" Accela Cota units.

Hunter Lab values in the Accela Cotas were comparable, with 1 minute in the 24" pan scaling to 2 minutes in the 60" pan. In this sense, the Accela Cota took a slightly greater time scale adjustment.

A comparison of the coating efficiencies of the Accela Cota and 67" HiCoater are presented in 60" Comparable Hunter Lab values were found after applying about 300 g of coating dispersion/kg of placebo tablet cores. With the difference in pan load and the equivalency in coating as determined by the Hunter Lab results, the only true difference is the time required to coat the tablets. Dividing the time required to apply 300 g of coating dispersion/kg of tablets by the tablet load gives a coating time of 0.458 min/kg of tablets for the Accela Cota and 0.435



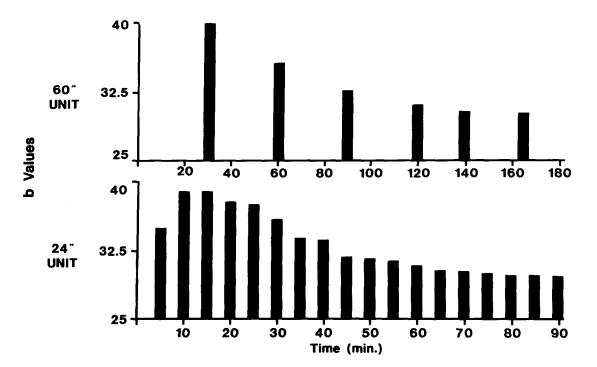


Figure 7:

Hunter b values vs time for the 60" and 24" Accela Cota units.

TABLE 4: Hunter Lab Values For 67" HiCoater and the 60" Accela Cota Runs with D. F. Anstead, Ltd. Speedpaste

Time	l value	Accela	a	value Accela	b value Accela		
(min)	- / 1 \	Cota	HiCoater		HiCoater	Cota	
10	/ 0)	1.6 <u>+</u> 1.9		28.7 <u>+</u> 7.1		
20	82.0 ± 5.3		5.9 <u>+</u> 4.2		36.5 <u>+</u> 4.5		
30	75.9 <u>+</u> 4.4	73.7 ± 4.2	10.5 ± 3.4	13.3 ± 2.9	39.3 <u>+</u> 1.2	39.8 ± 1.6	
45	71.7 ± 4.8		13.0 ± 2.8		38.4 ± 2.0		
60	67.7 ± 3.3	66.4 ± 1.8	14.9 ± 1.0	15.6 ± 0.5	36.7 ± 2.1	35.6 ± 1.4	
75	64.9 ± 2.5		15.1 ± 0.6	:	34.7 ± 1.9		
90	63.4 ± 2.0	62.7 ± 1.5	14.8 ± 0.9	13.8 <u>+</u> 1.2	33.7 ± 1.6	32.4 <u>+</u> 1.3	
105	62.1 ± 1.2		14.3 ± 0.7		32.6 ± 1.0		
120	60.9 ± 1.2	61.1 <u>+</u> 0.7	13.2 ± 1.0	12.3 ± 0.9	31.6 <u>+</u> 1.0	31.0 ± 0.6	
135	60.3 ± 0.8		12.8 ± 0.8		31.2 ± 0.6		
150	59.7 ± 0.6	60.1 ± 0.4	12.0 ± 0.8	11.0 <u>+</u> 0.7	30.6 <u>+</u> 0.5	30.3 <u>+</u> 0.4	
165	59.2 ± 0.5	59.9 ± 0.2	11.4 ± 0.7	10.5 ± 0.4	30.2 <u>+</u> 0.4	30.0 <u>+</u> 0.2	
180	58.9 ± 0.3		11.2 <u>+</u> 0.5		30.1 ± 0.3		
195	58.8 ± 0.5		11.0 ± 0.6		30.0 ± 0.4		
210	58.7 ± 0.4	1	10.7 ± 0.5		29.8 <u>+</u> 0.3		
230	58.6 ± 0.3		10.1 ± 0.3	j	29.6 ± 0.2		



TABLE 5: Summary

			Time			
			to Apply			
			300 g			
			Coating		Mear	ı
		Average	Material	Ηι	ınter	Lab
		Spray	per kg of		Value	es
	Load	Rate	Tablets	(n = 20)		20)
	<u>(kg)</u>	(g/min)	<u>(min)</u>	L	a	b
24" Accela Cota	10	33	90	58.8	11.0	29.5
60" Accela Cota	360	654	165	59.9	10.5	30.0
24" HiCoater	20	47	128	58.5	10.8	29.7
52" HiCoater	150	209	215	59.3	11.2	30.0
67" HiCoater						
Trial #1	480	689	209	58.7	10.7	29.8
Trial #2 ^(a)	480	692	208	61.0	8.7	30.0

(a) Crompton & Knowles Corporation Chroma-Kote; all other trials with D. F. Anstead, Ltd Speedpaste

min/kg for the HiCoater. These results are emphasized in Table 5 which summarizes all the discussed trials. As shown, Hunter Lab parameters are a sensitive measure of the efficiency of the dynamics occurring throughout the coating process. This technique may also be of benefit in the evaluation of coating system modifications. For example, equipment variables such as baffle design or formulation composition can be examined.

The Crompton and Knowles Chroma-Kote was only used in the 67" HiCoater. This material was examined as a Hunter Lab values for this possible alternate supply. material were 61.0 \pm 0.2, 8.9 \pm 0.4, and 30.1 \pm 0.2, The Anstead Speedpaste for L, a, and b respectively. had 58.7 \pm 0., 10.7 \pm 0.5, and 29.8 \pm 0.3 for L, a, and b respectively.

The pattern of changing Lab values measured throughout the coating runs was nearly identical for both sources of materials, as can be seen in the L value curves in The Chroma-Kote was subsequently fine tuned Figure 8. for a nearly perfect color match.



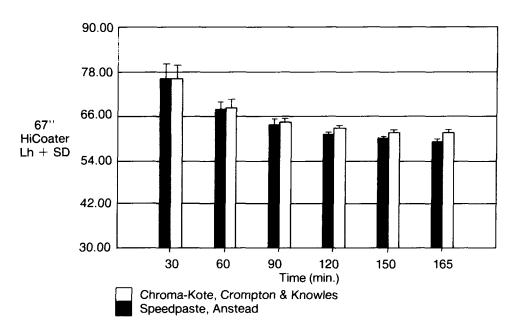


Figure 8:

Hunter L values vs time for the 67" HiCoater unit comparing pigment sources.

The final standard deviations of all Lab values were less than 0.5 for all runs included in this report. Therefore, the color variability within each batch was The usefulness of the Hunter Lab values evaluating alternate sources of color was also demonstrated.

For the equipment configurations and coating systems examined in this study the color efficiencies, as evaluated by Hunter Lab data, of the Thomas Engineering/Manesty Accela Cota and a Vector HiCoater However the batch size in the 67" Vector are similar. HiCoater was about 33% larger than in the 60" Accela the HiCoater required slightly less time Also, per kilogram of tablets to accomplish the same Where cost accounting factors are important variables in selection of manufacturing equipment or processes, the latter mentioned items may become extremely important.



ACKNOWLEDGEMENT

Presented in part at the Pharmaceutical Technology Section of the First National Meeting of the American Association of Pharmaceutical Scientists, November 2-6, 1986, Washington, DC

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