Comparison of a Laboratory and a Production Coating Spray Gun With Respect to Scale-up

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ABSTRACT

A laboratory spray gun and a production spray gun were investigated in a scale-up study. Two Schlick spray guns, which are equipped with a new antibearding cap, were used in this study. The influence of the atomization air pressure, spray gun-to tablet bed distance, polymer solution viscosity, and spray rate were analyzed in a statistical design of experiments. The 2 spray guns were compared with respect to the spray width and height, droplet size, droplet velocity, and spray density. The droplet size, velocity, and spray density were measured with a Phase Doppler Particle Analyzer.

A successful scale-up of the atomization is accomplished if similar droplet sizes, droplet velocities, and spray densities are achieved in the production scale as in the laboratory scale. This study gives basic information for the scale-up of the settings from the laboratory spray gun to the production spray gun. Both spray guns are highly comparable with respect to the droplet size and velocity. The scale-up of the droplet size should be performed by an adjustment of the atomization air pressure. The scale-up of the droplet velocity should be performed by an adjustment of the spray gun to tablet bed distance. The presented statistical model and surface plots are convenient and powerful tools for scaling up the spray settings if the spray gun is changed from laboratory spray gun to the production spray gun.

KEYWORDS: Atomization, film coating, spray gun, scale-up, design of experiments.

INTRODUCTION

The atomization of the coating dispersion is an important step during film coating. Many film defects can be ascribed by wrong settings of the atomization process. A general characterization of the atomization process was given by Lefebvre.[1]

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The influence of formulation factors such as density, surface tension, viscosity, and process factors such as spray rate, atomization air pressure, distance from spray gun, spray shape, spray gun design, and liquid nozzle diameter on droplet size, droplet velocity, and spray density was described by Aulton and Twitchell.[2] The polymer dispersion viscosity is one of the most important formulation variables. The effects of different parameters (spray rate, gun-to-tablet bed distance, atomization air pressure, spray shape, and spray gun design) on the film coat quality were examined for different spray guns.[3]

In addition to the atomization process, a combination of many other process and formulation variables is necessary for a good coating result.[4] In film coating, many different spray guns are used. Two-component jets are the most commonly used spray guns in film coating.

The scale-up of film coating processes is an important issue in the pharmaceutical industry. The key concept of scale-up in film coating is ensuring that the spray characteristics, tablet dynamics, and drying dynamics are all equivalent, and that these 3 elements are combined, so that the system dynamics are equivalent. A scale-up of the drying process in order to achieve equivalent thermodynamic conditions was described.[5,6] A comprehensive overview of scale-up approaches for a pan coating process was given by Porter.[7] The quality and specifications of the coated tablets produced in the laboratory scale should be transferred into the production scale. In scale-up, the settings for the laboratory spray gun should be carefully transferred to the production spray gun in order to achieve equivalent spray characteristics. Many parameters have to be taken into consideration. Scale-up includes changes in the spray rate, gun-to-tablet bed distance, nozzle diameter, spray gun model, and, consequently, a change in air flow rate for atomization and pattern air. In this study, the influence of the atomization air, gun to bed distance, spray rate, and solution viscosity on the droplet size, droplet velocity, and spray density were investigated for both, a laboratory spray gun and a production spray gun. Two spray guns from Schlick (Duesen-Schlick GmbH, Untersiemau/Coburg, Germany), both equipped with a new antibearding cap (ABC), were used in this investigation. The new geometry of the antibearding cap leads to a reduction in buildup of medium and less clogging. The established spray gun cap in horn-design (A) and the new

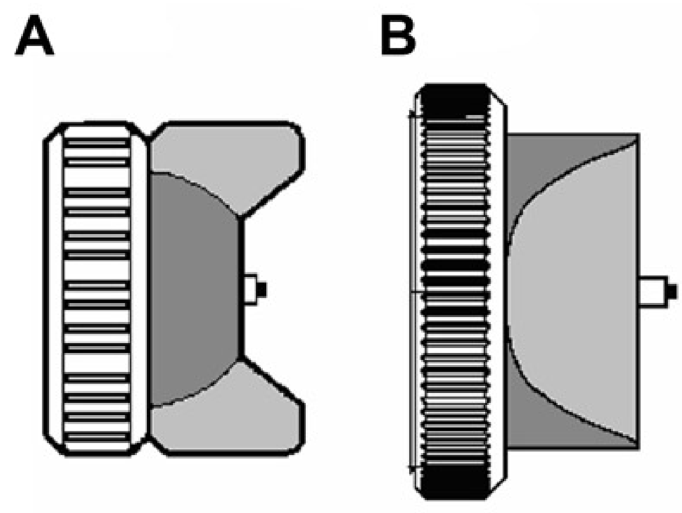

Figure 1. (A) Spray gun with a horn cap and (B) spray gun with antibearding cap.

spray gun cap with antibearding design (B) are illustrated in Figure 1. A detailed characterization of the new air cap was given by Gerstner.[8] These 2 Schlick spray guns are frequently used in pan coaters of different machine suppliers.

The droplet size, droplet velocity, and spray density were measured with a Phase Doppler Particle Analyzer. Furthermore, the width and height of the flat spray ellipse were also determined since the geometry of the flat spray cone was crucial for scale-up.

MATERIALS AND METHODS

Spray Solutions

Aqueous solutions of different viscosities based on hydroxypropylmethylcellulose (HPMC) (Pharmacoat 606, Synthapharm GmbH, Muelheim an der Ruhr, Germany) were used for all spray trials. HPMC used concentrations were 1.6%, 7.7% and 9.5%.

Preparation of HPMC Solutions

The exact amount of HPMC was weighted and suspended in well-stirred hot (95°C) tap water. After the whole powder was wetted, cool water was added to the end volume. Then, the solution was cooled down to 25°C.

Viscosity of HPMC Solutions

The HPMC solutions of 1.6%, 7.7%, and 9.5% were tested in a rotational viscometer at 25°C with a coaxial cylinder system M45 (Rotovisco RV20, Haake, Karlsruhe, Germany). At a shear rate of 300 seconds^{-1} the viscosities were determined to be 4, 88, and 175 mPa•s, respectively.

Spray Guns and Nozzle Diameter

The spray guns Schlick model 970/7-1 S75 ABC (Schlick, Untersiemau/Coburg, Germany) with a nozzle diameter of 1.0 mm as a laboratory spray gun (lab) and the Schlick model 930/7-1 S35 ABC with a nozzle diameter of 1.5 mm as a production spray gun (prod) were investigated. A peristaltic pump with 2 pump heads (model 505Di, Watson-Marlow, Falmouth, UK) was used.

Determination of Width and Height of the Spray Zone

The spray gun was mounted at the predetermined distance to an absorptive blue paper. The solution was sprayed onto the paper. The width and height of the spray zone were measured with a ruler (Figure 2).

Determination of Droplet Size, Droplet Velocity and Spray Density With a Phase Doppler Particle Analyzer

Phase Doppler Particle Analyzer (PDPA) is an optical technique to measure the size and velocity of spherical particles simultaneously. The PDPA is an extension of Laser Doppler

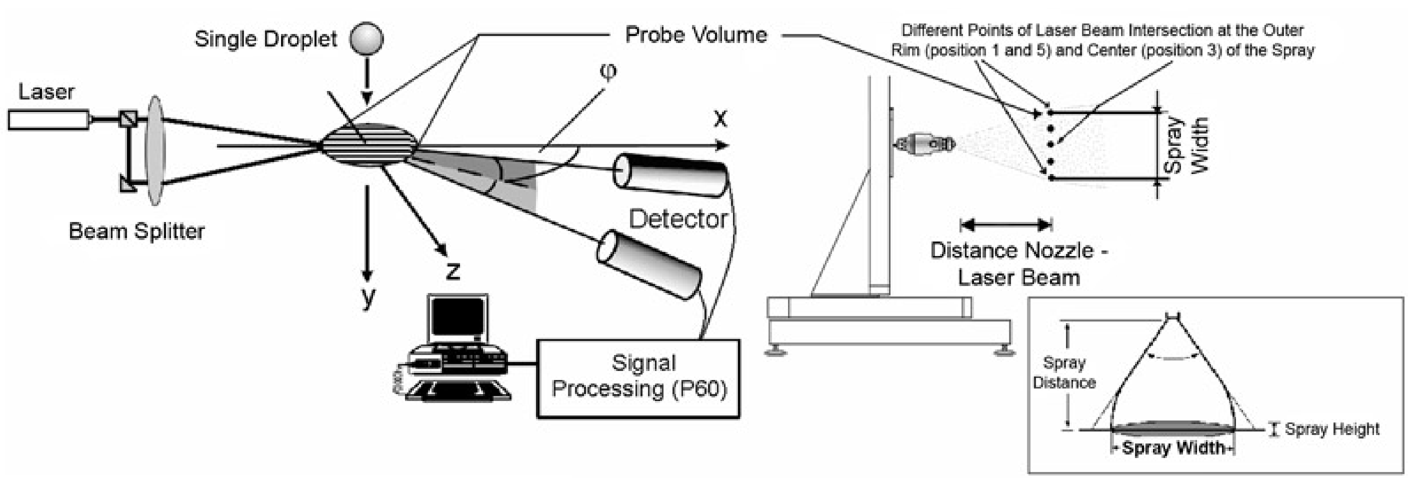

Figure 2. Experimental configuration.

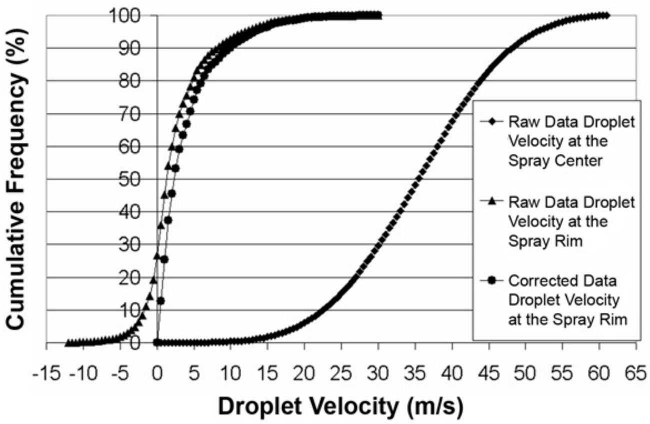

Figure 3. Raw data velocity distributions for droplets at the spray center and spray rim (with and without droplets of negative velocity).

anemometry, and the fundamental principles were explained by Ruck.[9] A further detailed description using PDPA was given in the literature.[10]

The droplet size, the velocity of the droplets, and the spray density were measured with a PDPA (with a Coherent Innova 70-5 Argon Ion Laser System wavelength $\lambda = 514.5$ nm, Laser Innovations [Santa Paula, CA], transmitting optics - fiber flow, Dantec Dynamics [Royal Portbury, UK], receiving optics detector 58N81 and processor P60, Dantec Dynamics). The scattering angle φ of the detector was 30° (Figure 2), and the focal lens length was 500 mm.

Experimental Configuration

A low-power laser beam is split into 2 beams that then intersect again at a point referred to the probe volume (Figure 2).The droplets pass the probe volume and the scattered light is analyzed by the detector. The left part of Figure 2 shows a common configuration of a PDPA, and the right part depicts the experimental configuration of the spray gun. Depending on the width of the spray, 5 until 9 positions (in Figure 2: outer rim positions are Position 1 and 5, center is Position 3) within the spray were measured. For this purpose, the position of the spray gun was adjusted in vertical direction by a motor.

For each setting according to the experimental plan (section statistical design) particles were determined until a maximum measurement time of 60 seconds or several 50 000 particles were reached. The droplet velocity was only measured along the y-axis (Figure 2).

Data Analysis and Pretreatment

Droplet Velocity

The median of the droplet velocity distribution ($v_{50\%}$) was used for the statistical evaluation of the droplet velocity. Close to the spray rim, negative droplet velocity values were observed (Figure 3). Droplets with negative velocity were eliminated prior to further evaluation. Examples of the droplet velocity distributions for the spray center and spray rim are shown in Figure 3. The median droplet velocity for the spray rim was calculated as the arithmetic mean of the values for the 2 outer measurement points (Figure 2).

Homogeneity of Droplet Velocity Within the Spray

The standard deviation of the droplet velocity ($s_{v_{50\%}}$) across the spray was calculated according to Equation 1 in order to characterize the full spray with respect to the droplet velocity distribution. The median droplet velocity as a function of the distance from the spray center is depicted in Figure 4.

$$s_{v_{50\%}} = \sqrt{\sum_{i=1}^{n} \frac{(v_{50\%i} - \bar{v}_{50\%})^2}{n-1}} \qquad (1)$$

where $v_{50\%}$ is the median of the velocity in the position i within the spray; $\bar{v}_{50\%}$ is the average of all median velocities; and n is the number of measured points in the spray (n = 5, 7, or 9).

Droplet Size

The median volume diameter (MVD) was used for the statistical evaluation of the droplet size. The droplet diameters are evaluated in a range of 0.1 to 120 µm. The MVD for the spray rim was calculated as the arithmetic mean of the values for the 2 outer measurement points (Figure 2).

Homogeneity of Droplet Size Within the Spray

The standard deviation of the MVD (s_{MVD}) across the spray width was used to express the variation in droplet size within the spray. The MVD subject to the distance from the

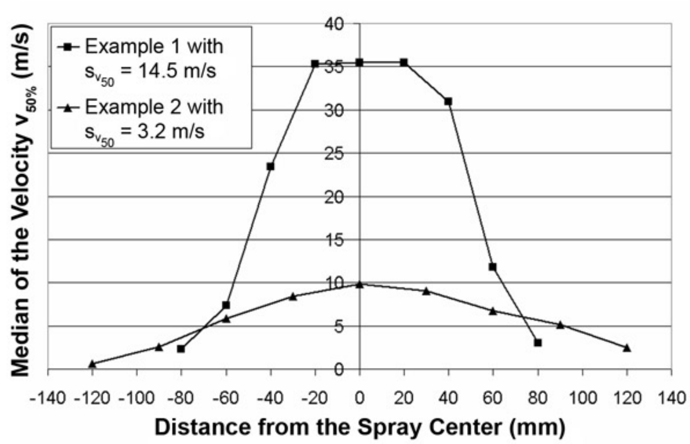

Figure 4. Examples of 2 velocity distributions in the spray (9 positions are measured).

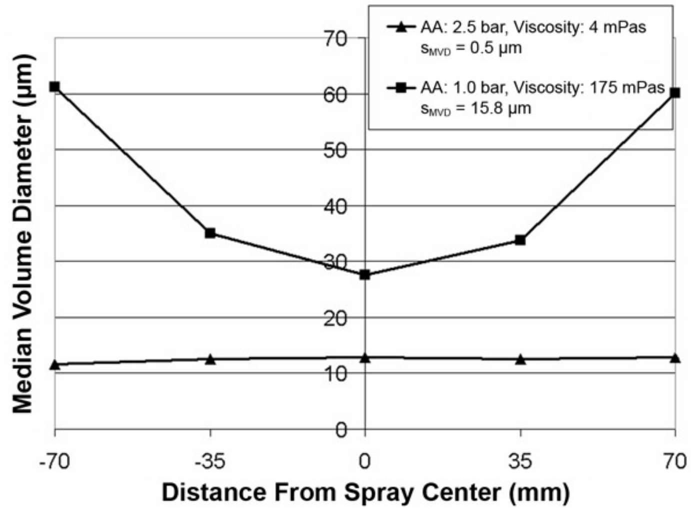

Figure 5. Examples of the distributions of the median volume diameter within the spray for 2 settings for the laboratory spray gun (distance 20 cm, spray rate 10 g/min).

spray center is depicted in Figure 5. The standard deviation within the spray was calculated according to Equation 2.

$$s_{MVD} = \sqrt{\sum_{i=1}^{n} \frac{(MVD_i - \overline{MVD})^2}{n-1}} \quad (2)$$

where MVD_i is the median volume diameter in position i within the spray; $\overline{MVD}$ is the average of all median volume diameters; and n is the number of measured points in the spray (n = 5, 7, or 9).

Determination of Spray Density

The spray density in cm³/cm²/s of the droplets could be measured with respect to a reference cross-sectional area. A detailed mathematical description to determine the spray density by PDPA was given in the literature.[11]

Statistical Design

For this study, a central composite face-centered design (CCFD) with 2 additional repetitions on the zero level and a total number of 27 runs was used. The variables including atomization air pressure (AA), spray rate (SprR), gun-to-tablet bed distance (ie, nozzle to laser beam distance, Dis), and solution viscosity (Vis) were investigated on 3 levels. Two CCFDs were created to investigate the 2 models of Schlick spray guns. The levels for the CCFDs with the laboratory spray gun and production spray gun are listed in Table 1.

The results were evaluated with the program Modde 7 (Umetrics, Umea, Sweden) using multilinear regression. The response variables were the droplet size expressed as the MVD (µm), the droplet velocity expressed as the median droplet velocity (m/s), the width and the height of the spray zone (cm), the spray density (cm³/cm²/s), and the standard deviation of all measured points within the spray for the MVD, the median velocity, and the spray density. The response Y was described as a regression model of the 4 independent variables (AA, SprR, Dis, and Vis) given by the general formula (Equation 3):

$$\begin{aligned} Y = {} & \beta_0 + \beta_1 AA + \beta_2 SprR + \beta_3 Dis + \beta_4 Vis \\ & + \beta_5 AA \times SprR + \beta_6 AA \times Dis + \beta_7 AA \times Vis \\ & + \beta_8 SprR \times Dis + \beta_9 SprR \times Vis + \beta_{10} Dis \times Vis \\ & + \beta_{11} AA^2 + \beta_{12} SprR^2 + \beta_{13} Dis^2 + \beta_{14} Vis^2 \quad (3) \end{aligned}$$

where $\beta_{1.....}\beta_{14}$ were the regression coefficients and β_0 was the regression constant. When the equation is presented with coded values, the magnitude of the coefficient specifies the change in response variable if the variable is altered from the lower level to zero or from zero to the upper level and the sign indicates the direction of the change. The model was simplified with a backward regression, which means that some terms were removed stepwise from the model if their P values were higher than .05 in order to increase the coefficient of determination (R^2_{adj}). First, the term with the highest P value was removed. A main factor was only eliminated if none of its interactions was significant.

Surface plots were used for the graphical illustration of the results.

RESULTS AND DISCUSSION

The results for the 2 CCFDs are summarized in Table 2. The regression constants and regression coefficients including the 95% confidence intervals for all response variables are given in Table 3.

Adjustment of the Pattern Air

The pattern air (PA) was adjusted to obtain an appropriate ellipsoid spray cone. Thereby, the pattern air was adjusted that a maximal spray width was obtained without forming a

Table 1. Variables for the Laboratory and Production Spray Gun CCFD*

Variable	−1		0		+1	
Spray gun	Lab	Prod	Lab	Prod	Lab	Prod
AA (bar)	1.00	1.00	1.75	2.00	2.50	3.00
SprR (g/min)	10	50	30	100	50	150
Dis (cm)	10	15	15	25	20	35
Vis (mPa•s)	4		88		175	

*CCFD indicates central composite face-centered design; Lab, laboratory spray gun; Prod, production spray gun; AA, atomization air; SprR, spray rate; Dis, gun-to-tablet distance; and Vis, viscosity.

Table 2. Results of the Study, Range of Yield Values*

CCFD	Unit	Production Spray Gun	Laboratory Spray Gun
Spray width	cm	11.0-24.0	7.00-30.0
Spray height	cm	4.0-10.0	3.0-8.0
MVD center	µm	15.9-55.3	12.8-33.1
MVD rim	µm	15.5-93.5	12.2-72.1
$v_{50\%}$ center	m/s	9.8-31.7	13.3-35.0
$v_{50\%}$ rim	m/s	1.3-6.6	0.7-3.6
Spray density center	cm³/cm²/s	0.016-0.100	0.0180-0.076
Spray density rim	cm³/cm²/s	0.0007-0.0275	0.000 23-0.0285
s_{MVD}	µm	0.4-19.3	0.5-18.8
$s_{v_{50\%}}$	m/s	3.2-11.9	4.6-15.9
Standard deviation spray density	cm³/cm²/s	0.005 89-0.039 80	0.007 10-0.062 22

*CCFD indicates central composite face-centered design; *MVD*, median volume diameter; $v_{50\%}$, median droplet velocity; s_{MVD}, standard deviation of the MVD; and $s_{v_{50\%}}$, standard deviation of the median droplet velocity.

dumbbell pattern. The settings for the pattern air pressure in bar and in norm cubic meter per hour (Nm^3/h) for the production spray gun and the laboratory spray gun are listed in Table 4. A lower air flow ratio of atomization and pattern air was observed for the laboratory spray gun. For the laboratory spray gun, a relative high amount of pattern air was required to form an appropriate spray cone compared with the production spray gun.

Air to Liquid Mass Ratio

Based on the density and the volume flow of air, the mass flow of atomization air was calculated. The air to liquid mass ratio was calculated as the ratio of the mass flow of atomization air to the mass flow of polymer solution. The calculated results are shown in Table 5 for both CCFDs.

The air to liquid mass ratio for a spray rate of 10 g/min was clearly higher than the other settings (Table 5). An increase in air to liquid mass ratio up to a value of around 4 leads to a reduction in droplet size. However, a further increase in the ratio is unlikely to result in any reduction in droplet size.[2]

Droplet Size

Different droplet diameters for the evaluation of atomization processes were described by Aulton and Twitchell.[2] The median volume diameter, the sauter mean diameter, or the length mean diameter were often used as mean diameters. In this study, the MVD was used for the evaluation of droplet size. Figures 6 and 7 show the surface plots for the influence of the atomization air and spray rate on the MVD. The absolute droplet size for all trials with the laboratory spray gun ranged from 13 to 33 µm in the spray center (Figure 6B). The highest MVD of 33 µm at the spray center was determined for a viscosity of 175 mPa•s, a spray rate of 50 g/min and an atomization air of 1.0 bar. The additional atomization effect of the pattern air in the spray center was probably a reason for these small droplets produced by the laboratory spray gun. A higher pattern air reduced the droplet size in the spray center for both Schlick spray guns.[12] The laboratory spray gun used a lower atomization air/pattern air ratio (Table 4) than the production spray gun to produce a flat spay cone. The higher pattern air mass flow could have caused smaller droplets for the laboratory spray gun. Since the droplets were already small, it was difficult to reduce the size further by an increase of atomization air.

In contrast, the production spray gun produced a maximum droplet size of 55 µm (Table 2). For this spray gun, an increase in atomization air pressure resulted in a remarkable reduction in droplet size. For the same air to liquid mass ratio the droplet size at the spray center was slightly bigger (~5-15 µm) for the production spray gun than for the laboratory spray gun. An often described equation[13] for predicting droplet sizes produced by pneumatic atomization is given in Equation 4 in adapted form:

$$D_s = \left[\frac{585 \cdot 10^3}{v}\right] \cdot \left[\frac{\sigma}{\rho}\right]^{0.5} + 1683\eta^{0.45} \cdot [\,\sigma \cdot \rho]^{-0.225} \cdot \left[\frac{1000}{J}\right]^{1.5} \quad (4)$$

where D_s is the surface mean diameter also referred to as the sauter mean diameter [µm]; v is the velocity of air relative to liquid at the nozzle exit [m/s]; σ is the liquid surface tension [N/m]; ρ is the liquid density [kg/m^3] for HPMC solution ~1020 kg/m^3; η is the liquid viscosity [Pa • s]; and J is the air to liquid volume ratio [dimensionless].

The droplet diameter after atomization depends on the physicochemical properties of the liquid (density, surface tension,

Table 3. Regression Constants and Regression Coefficients With 95% Confidence Interval in Parentheses for All Evaluated Response Variables*

	gun	Const	AA	SprR	Dis	Vis	AA• SprR	AA• Dis	AA• Vis	SprR•Dis	SprR•Vis	Dis• Vis	AA²	SprR²	Dis²	Vis²	R^2_{adj}
MVD (center, µm)	L	29.446 (0.847)	–0.528 (0.607)†	2.267 (0.607)	1.000 (0.607)	4.772 (0.774)	—	—	—	0.938 (0.644)	—	—	—	—	—	–7.254 (1.361)	0.959
	P	36.682 (0.967)	–5.444 (0.645)	3.856 (0.646)	1.698 (0.654)	7.093 (0.890)	—	–1.350 (0.685)	—	—	—	1.152 (0.779)	2.853 (1.500)	—	—	–6.398 (1.941)	0.979
MVD (rim, µm)	L	58.285 (3.403)	–5.818 (2.473)	9.164 (2.442)	—	13.608 (3.112)	—	—	3.389 (2.945)	—	—	—	—	—	—	–14.331 (5.472)	0.917
	P	75.689 (5.605)	–11.325 (4.022)	9.479 (4.074)	—	15.131 (5.126)	—	—	—	—	–6.165 (4.851)	—	—	—	—	–14.835 (9.012)	0.853
s_{MVD} (µm)	L	13.912 (2.049)	–2.295 (1.470)	2.386 (1.470)	—	3.338 (1.874)	—	—	—	—	—	—	—	—	—	–4.548 (3.293)	0.688
	P	15.743 (1.933)	–2.235 (1.387)	2.196 (1.405)	—	2.946 (1.768)	—	—	—	—	–2.570 (1.673)	—	—	—	—	–4.275 (3.108)	0.722
$v_{50\%}$ (center, m/s)	L	21.121 (0.292)	3.772 (0.205)	–1.017 (0.205)	–4.935 (0.205)	0.751 (0.233)	–0.275 (0.218)	–0.894 (0.218)	—	0.284 (0.218)	—	—	—	—	1.591 (0.355)	—	0.994
	P	18.249 (0.332)	5.401 (0.233)	–0.924 (0.233)	–4.415 (0.236)	0.159 (0.265)†	—	–0.909 (0.247)	—	0.277 (0.247)	—	0.291 (0.281)	—	—	1.070 (0.404)	—	0.994
$v_{50\%}$ (rim, m/s)	L	1.859 (0.276)	0.579 (0.338)	–0.368 (0.338)	—	—	—	—	—	—	—	—	—	—	—	—	0.374
	P	1.740 (0.433)	0.476 (0.304)	–0.485 (0.304)	–0.832 (0.308)	0.364 (0.346)	–0.686 (0.322)	—	—	—	—	–0.508 (0.367)	—	—	1.290 (0.526)	—	0.797
$s_{v_{50\%}}$ (m/s)	L	8.396 (0.458)	1.877 (0.324)	–0.583 (0.324)	–2.553 (0.324)	—	—	–0.742 (0.344)	—	—	—	—	—	—	0.888 (0.561)	—	0.946
	P	6.943 (0.127)	2.089 (0.153)	–0.245 (0.153)	–1.901 (0.155)	—	—	–0.536 (0.163)	—	—	—	—	—	—	—	—	0.984
Spray density (center, cm³/cm²/s)	L	0.057 (0.005)	—	0.0213 (0.0036)	–0.0042 (0.0036)	–0.0018 (0.005)†	—	—	—	—	—	—	—	—	—	–0.0147 (0.0108)	0.760
	P	0.072 (0.007)	—	0.0207 (0.0049)	–0.0156 (0.0049)	0.0016 (0.0063)†	—	—	—	—	—	—	—	—	—	–0.0227 (0.0111)	0.843
Standard deviation spray density (cm³/cm²/s)	L	0.0280 (0.0036)	—	0.0106 (0.0044)	–0.0057 (0.0044)	—	—	—	—	—	—	—	—	—	—	—	0.539
	P	0.0270 (0.0028)	—	0.0069 (0.0020)	–0.0071 (0.0020)	—	—	—	—	–0.0023 (0.0021)	—	—	—	–0.0074 (0.0035)	—	—	0.835
Spray width (cm)	L	12.564 (0.804)	–1.615 (0.980)	3.347 (0.980)	1.667 (0.967)	2.626 (1.100)	–1.438 (1.026)	—	–1.282 (1.167)	—	1.352 (1.167)	—	—	—	—	—	0.805
	P	14.533 (1.148)	–2.165 (0.834)	1.194 (0.823)	3.111 (0.823)	2.348 (1.050)	—	—	–1.026 (0.993)	—	—	—	—	—	—	4.248 (1.845)	0.830
Spray height (cm)	L	4.935 (0.372)	—	0.889 (0.262)	0.835 (0.265)	0.317 (0.297)	—	—	—	0.375 (0.277)	—	0.426 (0.316)	—	–0.504 (0.453)	—	—	0.807
	P	5.710 (0.630)	—	—	1.833 (0.452)	0.214 (0.576)†	—	—	—	—	—	—	—	—	—	2.019 (1.013)	0.768

*Const indicates regression constant; AA, atomization air; SprR, spray rate; Dis, gun-to-tablet distance; Vis, viscosity; MVD, median volume diameter; L, laboratory spray gun; P, production spray gun; s_{MVD}, standard deviation of the MVD; $v_{50\%}$, median droplet velocity; and $s_{v_{50\%}}$, standard deviation of the median droplet velocity.

†Not significant at 95% confidence level.

Table 4. Settings for the Air Pressure, the Corresponding Air Flow, and the Ratio of the Air Flow*

	Production Spray Gun					Laboratory Spray Gun				
CCFD	AA		PA		AA/PA	AA		PA		AA/PA
Levels	Bar	Nm^3/h	Bar	Nm^3/h		Bar	Nm^3/h	Bar	Nm^3/h	
–1	1.0	7.8	1.0	4.7	1.7	1.0	3.1	1.5	3.6	0.9
0	2.0	12.0	2.0	7.1	1.7	1.75	4.3	2.0	4.3	1.0
+1	3.0	16.0	3.0	9.3	1.7	2.5	5.3	2.8	5.3	1.0

*CCFD indicates central composite face-centered design; AA, atomization air and PA, pattern air.

and viscosity), the velocity of the air relative to the liquid at the atomization nozzle exit, and the air flow to liquid volume ratio. The higher the ratio is, the smaller the diameter of the droplets.

The droplet size at the spray center was significantly influenced by all main variables (Table 3). Both spray guns resulted in large linear and quadratic coefficients for the viscosity. A higher viscosity led to larger droplets for both spray guns, whereas the coefficient for the production spray gun was higher than the laboratory spray gun at the spray center (Table 3). The absolute higher distance interval for the production spray gun might be the reason because a higher gun to bed distance intensified the influence of the viscosity on the droplet size, which could be seen from the interaction viscosity to distance (Table 3). The influence of the atomization air on the droplet size was different for both spray guns as already discussed.

In addition, the droplet size at the spray center increased with increasing distance and spray rate. These results coincided with the results reported in literature.[2] With increasing distance, the droplet size increased because of the collision and coalescence.

The droplet size at the spray rim was clearly bigger than in the spray center (Figure 7A and B). The change in droplet size at the spray rim was obviously more influenced by the variables than in the spray center. An increase in viscosity and spray rate led also to an increase in the droplet size, as the magnitude of the coefficient was twice as high for both spray guns at the spray rim compared with the spray center. As expected, a higher atomization air pressure resulted in a reduction in droplet size, and the influence of the atomization air on the laboratory spray gun was clearly higher than at the spray center. The bigger droplet size (up to 72 μm) might be the reason for the influence of atomization air on the droplet size of the laboratory spray gun at the spray rim. These bigger droplets disintegrated easier with increasing atomization air than the small droplets (maximum 33 μm) in the spray center.

An influence of the distance on the droplet size at the spray rim was not observed for both spray guns. The MVD at the spray rim was independent of the gun-to-bed distance, and the absolute value of the coefficient for the gun to bed distance at the spray center was low (less than 2 μm). Hence, it could be assumed that the factor gun to bed distance was negligible for the scale-up of the droplet size for both spray guns. Therefore the droplet size should be scaled up by adjusting the atomization air and considering the spray rate.

However, the droplet velocity and spray density were affected by the distance that is described in the following sections. Surface plots for the influence of viscosity and distance on the MVD at the spray center are shown in Figure 8.

Table 5. Calculated Air-to-Liquid Mass Ratios for Laboratory and Production CCFD*

		Laboratory CCFD			Production CCFD		
Atomization Air	Bar	1.00	1.75	2.50	1.00	2.00	3.00
	Nm^3/h	3.1	4.3	5.3	7.8	12.0	16.0
Spray Rate (g/min)		Air-to-Liquid Mass Ratio					
10		6.2	8.6	10.6	—	—	—
30		2.1	2.9	3.5	—	—	—
50		1.2	1.7	2.1	3.1	4.8	6.4
100		—	—	—	1.6	2.4	3.2
150		—	—	—	1.0	1.6	2.1

*CCFD indicates central composite face-centered design.

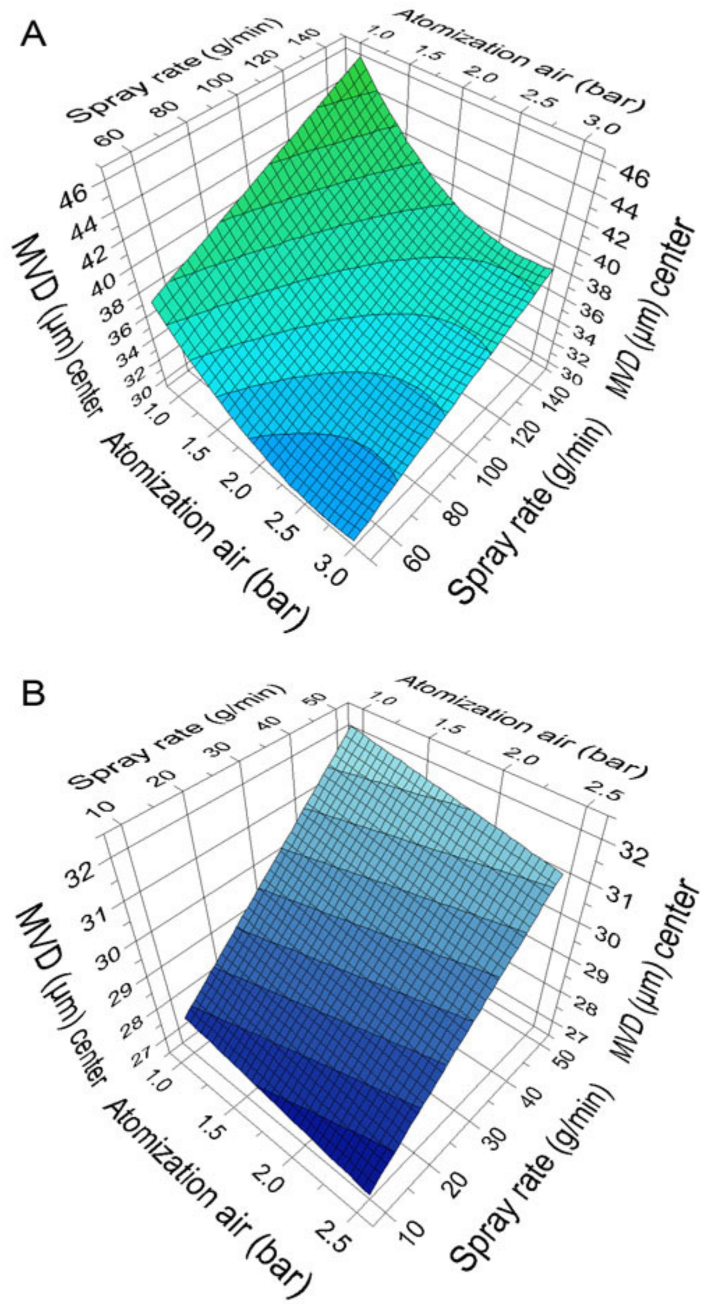

Figure 6. Response surface plots for median volume diameter at the spray center (viscosity = 88 mPa•s, distance = 15 cm). (A) Production spray gun (B) Laboratory spray gun. MVD indicates median volume diameter.

Homogeneity of Droplet Size Within the Spray

For a good coat quality it is necessary that the droplets are all of a consistent size or have a small size range. The standard deviation from all measurement points of the MVD across the spray is an indicator for the uniformity of the droplet size within the spray. An increase in viscosity and spray rate led to a higher standard deviation of MVD for both spray guns (Table 3). Both spray guns are in good agreement with respect to these parameters. The standard deviation decreased with increasing atomization air.

Droplet Velocity

The median of the velocity distribution was used to evaluate the droplet velocity. The droplet velocities were normally distributed at the spray center. The main trajectory of the droplets at the spray center was in y-direction (Figure 2). In contrast, the trajectory of the droplets at the spray rim was in y- and x-direction. In this study, the PDPA only measured the velocity along the y-axis that led to a slightly lower measured absolute velocity at the spray rim, as the correct

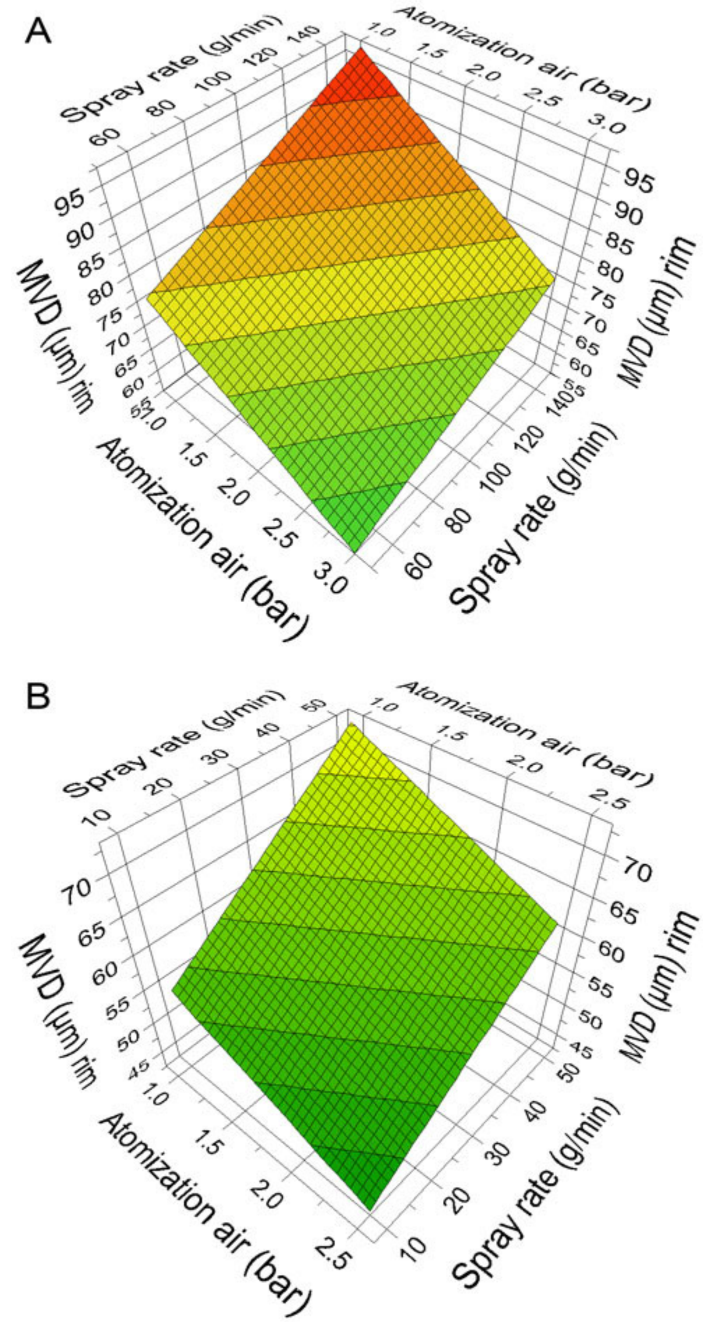

Figure 7. Response surface plots for median volume diameter at the spray rim (viscosity = 88 mPa•s, distance = 15 cm). (A) production spray gun (B) laboratory spray gun. MVD indicates median volume diameter.

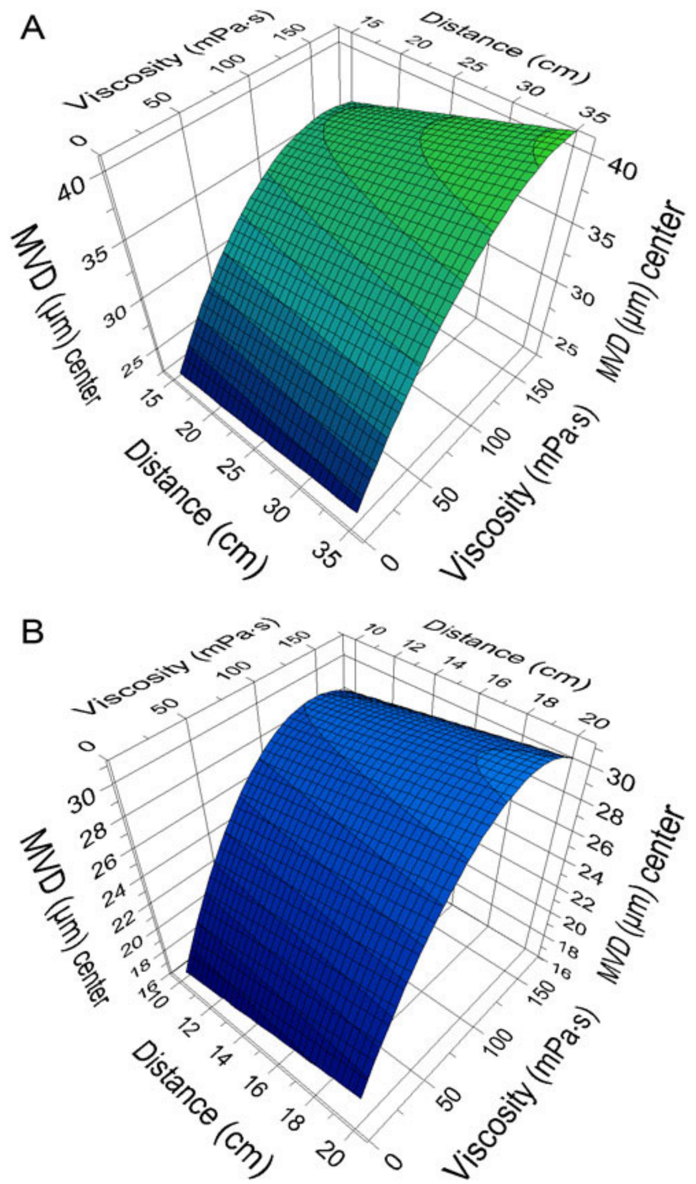

Figure 8. Response surface plots for the median volume diameter at the spray center. (A) Production spray gun with AA 2.0 bar, PA 2.0 bar, and SprR 100 g/min; (B) Laboratory spray gun with AA 1.75 bar, PA 2.0 bar, and SprR 30 g/min. MVD indicates median volume diameter.

velocity was calculated from the vector of the x-velocity and y-velocity components. Negative velocities due to turbulences were observed at the spray rim. These droplets passed through the laser beam twice. Thus, droplets with a negative velocity were eliminated from the evaluation.

The coefficients from the CCFDs for the droplet velocity at the spray center and spray rim are listed in Table 3. The atomization air and the gun to bed distance were the main parameters that influenced the droplet velocity. The droplet velocity increased with increasing atomization air for both spray guns, whereas the coefficient for the atomization air for the production spray gun was higher because of the larger factor space in the CCFD of the production spray gun. The droplet velocities were in similar ranges for same atomization air pressures and gun to bed distances for both spray guns (Figure 9). The average droplet velocity drops rapidly after leaving the spray gun, which is illustrated in the surface plots. The droplet velocity at the spray rim was significantly influenced by the atomization air and the gun-to-tablet bed distance for both spray guns; however, the magnitudes of the coefficients were clearly lower at the spray rim (Table 3).

The influence of the atomization air on the coat quality was investigated by Twitchell.[14] The film coat roughness was determined in this study depending on the atomization air. The film coat roughness decreased with increasing atomization air pressure, whereby the droplets possessing greater

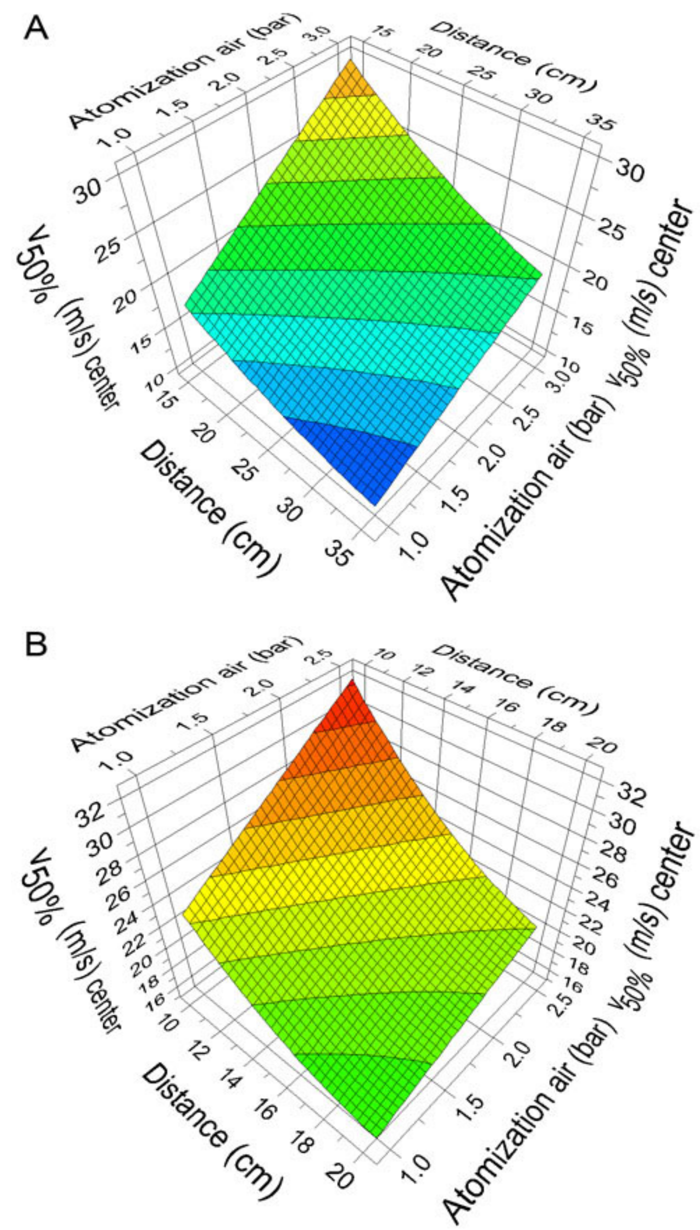

Figure 9. Response surface plots for the droplet median velocity $v_{50\%}$ at the spray center, viscosity 88 mPa•s. (A) Production spray gun, SprR 100 g/min; (B) Laboratory spray gun, SprR 30 g/min.

momentum when they impinge on the substrate result in an enhanced droplet spreading that leads to a smoother coat.

The change in viscosity did not influence the droplet velocity at the spray center of the production spray gun and led to a very low increase of droplet velocity of the laboratory spray gun. An increase in the spray rate led to a small (~1 m/s) decrease in droplet velocity in the center (Table 3).

The gun to bed distance should be used to scale up the droplet velocity and can be set according to the statistical models derived in the present study. A scale-up of the spray rate and the gun to bed distance should be also performed with respect to the total spray area, which determines the number of passes of tablets through the spray zone and the amount of coating solution that is applied per pass.[15]

Homogeneity of Droplet Velocity in the Spray

The droplet velocity at the spray rim was definitely lower, because the droplets were decelerated more effectively at the spray rim. The velocity difference between the center and the spray rim can be 33 m/s. These differences can reduce the coating quality because the droplets impinge at different speeds on the tablet surface. Hence, it is desirable to choose the settings that minimize the differences in velocity by an acceptable droplet velocity at the spray center (Figure 4). If the atomization air was increased, the variation of the droplet velocity within the spray also increased (Table 3). With increasing distance from the spray gun, the velocity was slower (Figure 9). This effect led to a compensation of the droplet velocity at the spray center with the droplets at the spray rim and, consequently, decreased the standard deviation of the droplet velocity within the spray. In addition, a change in viscosity did not affect the variation in droplet velocity within the spray for both spray guns. The absolute standard deviation of the median velocity of the production spray gun was slightly lower due to the absolute higher distance.

Spray Width and Height of the Spray Zone

The width of the spray zone was significantly influenced by all main factors for both spray guns (Table 3). Increasing the viscosity, distance, and the spray rate led to a higher spray width for both spray guns. At higher viscosity and spray rate, the droplet size increased. These bigger droplets have a higher working surface for the air. Thus, the flat spray could be wider and the spray angle increased.

In contrast, increasing the atomization air led to a smaller spray width. The lower coefficient for the gun to bed distance for the laboratory spray gun was due to the smaller factor space (5 vs 10 cm) in the laboratory scale design. The spray width of the production spray gun was less influenced by the spray rate compared with the spray width of the laboratory spray gun. Furthermore, an interaction between the viscosity and the atomization air for both spray guns could be observed. If the atomization air was on the low level, the spray width was more affected by the viscosity.

The spray height was significantly influenced by the gun to bed distance for both spray guns. A distance increase led to a higher spray height for the production spray gun (15-25 cm) of ~2 cm (Table 3) and for the laboratory spray gun (10-15 cm) of 1 cm. An increase in spray height results in a higher surface time per pass (ie, the time that tablets spend per pass in the spray zone).[16]

Spray Density

The spray rate was the main factor influencing the spray density in the center and rim of both spray guns. The spray

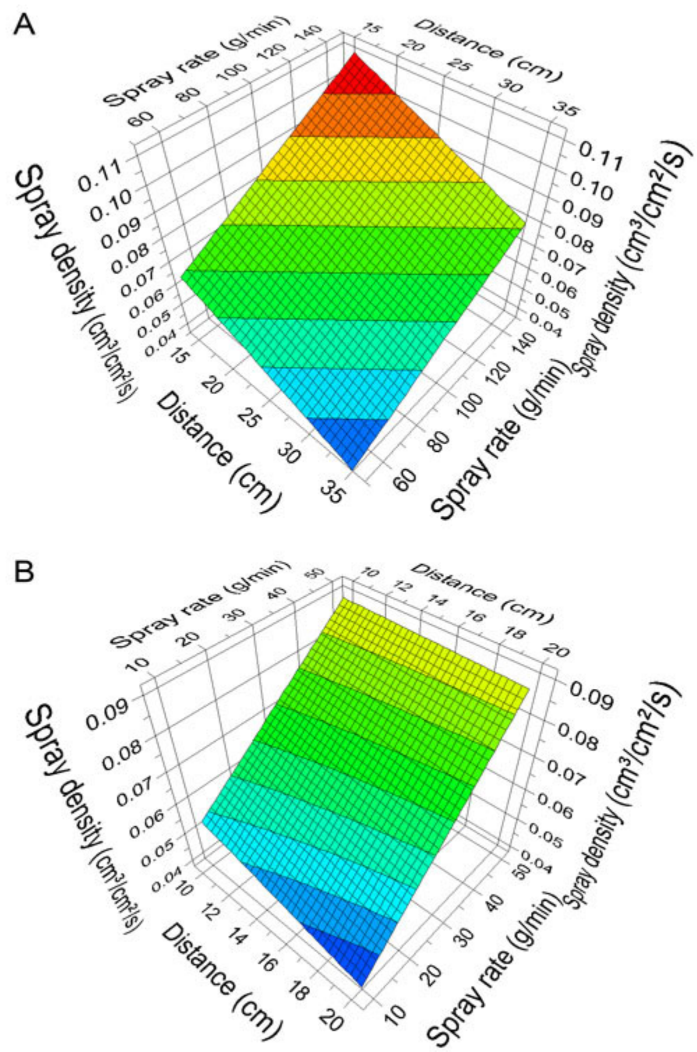

Figure 10. Response surface plots for the spray density of the spray density in the center, viscosity 88 mPa•s. (A) Production spray gun for atomization air (AA), 2.0 bar; (B) Laboratory spray gun for AA 1.75 bar.

density increased with increasing spray rate in center and rim and decreased with increasing distance as a consequence of the expansion of the spray. A decrease in spray density with increasing distance for both spray guns at the spray rim could not be observed. The change of the gun to bed distance had more influence on the spray density in the center of the production spray gun than the laboratory spray gun (Table 3) because of the absolute higher distance setting for the production spray gun. Furthermore, a quadratic influence of the viscosity was found for both spray guns.

Figure 10 shows the surface plot of the spray density. A negligible difference in the absolute spray density range was observed between the compared spray guns (Table 2). The spray density of the production spray gun was slightly higher because of the absolute higher spray rates. The parameters that affected the homogeneity of the spray density are listed in Table 3. The same parameters affected the spray density as well as the distribution within the spray. The gun to bed distance should be increased and the spray rate decreased in order to achieve an even spray density across the full spray.

CONCLUSIONS

The droplet size and velocity are the basic parameters and should be transferred in a narrow range from laboratory spray gun to production spray gun. The gun to bed distance has a low influence on the droplet size, and the droplet size should be therefore scaled up by adjusting the atomization air and considering the spray rate. The gun to bed distance should be used to scale up the droplet velocity in order to achieve the same droplet velocity in the production scale. The proposed scale-up approaches can certainly be used among similar laboratory and production 2 component nozzles of other suppliers.

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