Investigating the Influence of Inlet Air Temperature and Solid Matter Content on the Total Spraying Time in a Side Vented Pan Coating Process

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Abstract Summary

Film coating dispersions of four different concentrations of the ready-to-use film coating material Kollicoat® IR Carmine were tested in two different side vented pan coaters. The influence of varying the inlet air temperature was tested as well. For each process, the maximum spray rate was determined to find the optimal solid matter content leading to shortest process time.

The highest spray rates could be found for a solid matter content of 25 %. Dispersions with both lower and higher solid contents resulted in lower maximum spray rates.

This result was found to be independent from the inlet air temperature, as the trials showed that a solid matter content of 25 % was optimal for all three temperatures tested. However, it could be seen that an increase in temperature did not necessarily lead to a shorter process time.

Introduction

In film coating processes, two parameters are known to decrease the total spraying time: high solid matter content (SMC) and elevated inlet air temperature. This study was to investigate whether there is an optimal setting for both variables.

The measure for the total spraying time is the spray rate. Therefore, the dependency of this parameter on SMC and inlet air temperature was investigated.

Experimental Methods

Materials

The ready-to-use coating material Kollicoat® IR Carmine (BASF SE, Germany) was tested. The formulation of the placebo cores is shown in Table 1.

Ingredients		Quantity [%]
Ludipress® LCE	(BASF SE)	79.5
Kollidon® VA64	(BASF SE)	20.0
Mg-stearate	(Bärlocher)	0.5

Table 1: Core formulation (round shaped biconvex, diameter 11 mm).

Equipment

Two types of side vented pan coaters offering batch sizes of 5 and 40 kg were used:

- XL Lab 01, Manesty, Liverpool, U.K.
- Perfima Lab, I.M.A. S.p.A., Bologna, Italy

To perform the rheological investigations, the Thermo Scientific HAAKE RotoVisco 1 rotational rheometer, from Thermo Fisher Scientific, Karlsruhe, Germany with liquid temperature control unit TCL/Z for concentric cylinder measuring geometries was used in combination with a circulator HAAKE DC30-K10.

Methods

Kollicoat® IR Carmine dispersions with concentrations of 15, 20, 25 and 30 % were applied using inlet air temperatures of 50, 60 and 70 °C. Each experiment was carried out in both types of equipment. After applying a first layer of coating dispersion onto the cores (about 0.5–1% weight gain) for each setting, the maximum spray rate was determined. [1]The decisive criterion was the surface quality, which was appraised visually, while stepwise increasing the spray rate. First signs of surface roughness indicated that the maximum spray rate had just been exceeded. This means that the pump speed just below this setting resulted in the highest applicable spray rate.

$$\frac{\textit{batch size [g]} \times \textit{weight gain}}{\textit{spray rate}\ \frac{g}{min} \times \textit{solid matter content}} = \textit{total spraying time}$$

Equation 1: Calculation of the total spraying time.

	XL Lab 01	Perfima Lab
Size	Small scale	Pilot scale
Batch size	5 kg	40 kg
Drum speed	12 rpm	7 rpm
Inlet air quantity	450 m³/h	1,060 m³/h
Type of nozzle	OptiCoat®	Schlick 970/7-1 S75
Number of nozzles	1	2
Bore diameter	0.8 mm	1.5 mm
Atomisation air pressure	2.4 bar	2.0 bar

Table 2: Settings for the side vented pan coating processes.

Based on the maximum spray rate, the total spraying time was calculated, considering a final weight gain of 3.5 % (Equation 1). The parameters of the coating processes are summarised in Table 2.

Results and Discussion

XL Lab 01

The results show, that for SMCs from 15 to 25 % at inlet air temperatures of 50 and 60 °C the maximum spray rate slightly increased. In contrast, at a temperature of 70 °C the maximum spray rate decreased with increasing SMCs. Interestingly, to ensure a smoothly coated tablet surface using the dispersion with a SMC of 30 %, the resulting maximum spray rate was about 50 % lower at all temperature settings (Figure 1).

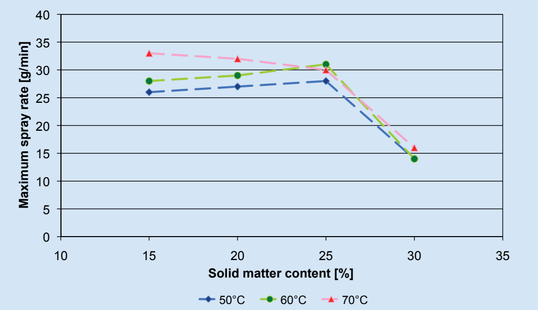

Figure 1: Dependency of maximum spray rate on solid matter content (XL LAB 01).

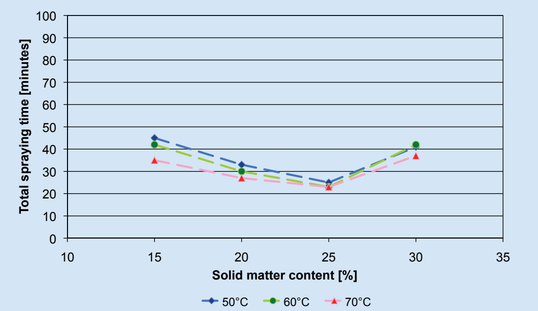

Figure 2: Dependency of total spraying time on solid matter content (XL LAB 01).

The data suggest that the shortest total spraying time can be realised by applying a dispersion with a SMC of 25 % at 60 °C. A further increase in inlet air temperature did not result in a higher maximum spray rate (Figure 2).

This is also confirmed by the data on the influence of inlet air temperature: at SMCs below 25 % an increase in temperature resulted in a higher maximum spray rate, whereas at SMCs higher than 25 % the influence on the maximum spray rate was less pronounced.

Perfima Lab

The results of the trials in pilot scale show as well that with 25 % SMC the shortest total spraying time can be realised (Figure 4).

Although the influence of inlet air temperature on the maximum spray rate was similar in both types of equipment, two important differences could be found: firstly, compared to the results in the XL Lab 01 the slope of the curve indicating the increase in maximum spray rate is distinctively higher for SMCs of 15, 20 and 25 %. Secondly, in contrast to the small scale trials, at a temperature of 70 °C the maximum spray rate increased at SMCs of up to 25 % as well. Interestingly, for inlet air temperatures of 60 and 70 °C the same maximum spray rate could be found with a SMC of 25 % (Figure 3).

As already observed in small scale trials, an increase of SMC to 30 % resulted in a steep decrease of the maximum spray rate.

The fact that in both sets of trials the highest spray rate was realised at a SMC of 25 % is presumably related to the increasing dynamic viscosity with higher SMCs (Figure 5). As this characteristic follows a logarithmical function, the increase in viscosity between SMCs of 25 and 30 % is markedly higher than between lower SMCs. This changes the coating properties distinctively, resulting in a lower maximum spray rate, which was not compensated by the higher SMC of the dispersion.

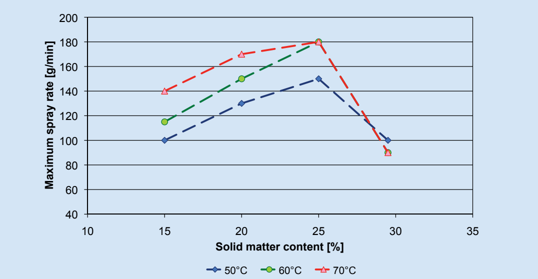

Figure 3: Dependency of maximum spray rate on solid matter content (Perfima Lab).

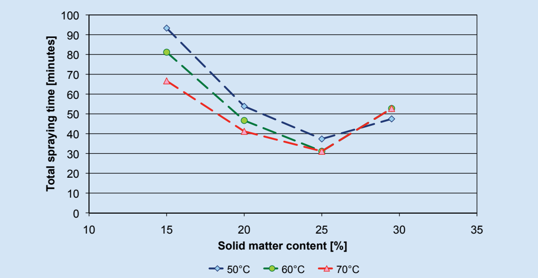

Figure 4: Dependency of total spraying time on solid matter content (Perfima Lab).

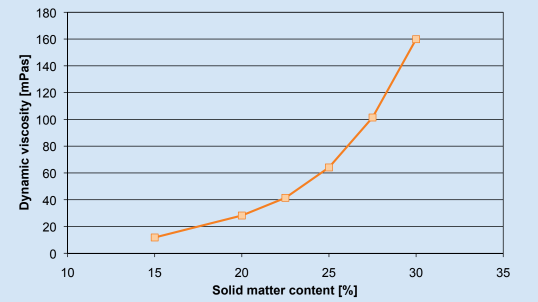

Figure 5: Dependency of dynamic viscosity on solid matter content of Kollicoat® IR Carmine.

Conclusion

In general, an increase in SMC leads to shorter process times. This is caused by the possibility of higher spray rates as well as a smaller amount of dispersion which has to be applied. The optimal SMC for Kollicoat® IR Carmine with regard to spraying time optimisation was found to be 25 % at all temperatures tested.

At a SMC of 30 %, the increase in dynamic viscosity changes the spraying behaviour of the dispersion markedly, resulting in a distinctively longer spraying time.

Although at lower SMCs, an increase of inlet air temperature resulted in higher spray rates, at the optimal SMC of 25 % a temperature elevation from 60 to 70 °C did not shorten the process time any more. Therefore, an inlet air temperature of 60 °C can be considered as the optimal setting for Kollicoat® IR Carmine in small as well as pilot scale.

References

1. Cech, T.; Kolter, K.; Comparison of the coating properties of instant release film coating materials using a newly developed test method – the Process-Parameter-Chart; 3. Pharmaceutical Science World Congress; **2007;** Amsterdam; The Netherlands

The 37th Annual Meeting and Exposition of the Controlled Release Society, July 10–14, 2010, Oregon Convention Center, Portland, Oregon, U.S.A.
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