Comparing the Up Scaling Characteristics of an Instant Release Film Coating Formulation in Solid Wall and Side Vented Pan Coaters

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Abstract Summary

In film coating processes the limiting factor in regard to spray rate is the maximum amount of liquid carrier that can be applied onto a single core while it is passing the spray pattern. This can be described by the ratio of surface time and spray rate per nozzle. Therefore, the following approach for scaling up coating processes which is independent of the type of equipment was suggested: keep circumferential speed and spray rate per nozzle constant (i.e. constant surface time). At the same time, to maintain a sufficient drying, the inlet air quantity per nozzle has to be kept constant during scale up as well.

As the results show, this approach can be applied for up scaling procedures in horizontal side vented and solid wall pan coaters.

Introduction

Several approaches were developed on how to conduct a product transfer from lab or pilot to production scale. [1]One method could be, to calculate the amount of dispersion applied onto a single core while it is passing the spray pattern and thereby keeping surface time constant.

As it is difficult to apply the results of these calculations on a practical base, the constant ratio of spray rate per nozzle can be taken as a measure for this parameter. [1]Based on this consideration the following approach for scale up was suggested: firstly, to maintain the same moisture exposure in all scales by keep the circumferential speed and the spray rate per nozzle constant and secondly, to maintain an efficient drying by keeping the amount of process air per nozzle constant. [2]For side vented pan coaters, it was shown that comparable results in different scales could be achieved.

This paper is to investigate whether this approach could be applied on coating processes performed in solid wall coaters as well.

Experimental Methods

Equipment

The side vented pan coaters Perfima Lab with 60 litre drum and Perfima 200 as well as the solid wall coaters GS HP 25 and GS 300 (all I.M.A. S.p.A., Italy) were used.

Materials

[3]The ready-to-use coating material Kollicoat® IR Carmine (BASF SE, Germany) was used with an optimal solid matter content of 25 %.

Two types of tablet cores differing in regard to composition, shape and size were used in the coating trials (Table 1 and 2).

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

Table 1: Core formulation of the round shaped tablets (mass: 300 mg; surface: 212 mm²).

Ingredients		Quantity [%]
Caffeine, gran. 0.2-0.5	(BASF SE)	15.5
Ludipress® LCE	(BASF SE)	74.0
Kollidon® CL-F	(BASF SE)	5.0
Kollidon® VA64 Fine	(BASF SE)	5.0
Mg-stearate	(Bärlocher)	0.5

Table 2: Core formulation of the football shaped tablets (mass: 450 mg; surface: 310 mm²).

Methods

For the application of the up scaling approach, the maximum spray rates in small scale for both types of equipment (Perfima Lab and GS HP 25) were determined. 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. Based on these results, the coating parameters for large scale were calculated.

Results and Discussion

Side vented pan coater

For the coating process of the round shaped placebo cores in the Perfima Lab coater, the maximum spray rate at 50 °C inlet air temperature was determined. Based on this value, the process settings for the large scale coating process in the Perfima 200 were calculated according to the theoretical scale up approach (Table 3).

	Optimal settings Perfima Lab	Calculated settings Perfima 200
Batch size	40 kg	140 kg
Number of nozzles	2	4
Drum speed	7 rpm	5 rpm
Circumferential speed	361 mm/s	349 mm/s
Inlet air temperature	50 °C	50 °C
Inlet air quantity	1,060 m³/h	2,120 m³/h
Maximum spray rate	150 g/min	300 g/min

Table 3: Settings for the side vented pan coating processes.

Independent from the batch size and the type of coater, a smooth and shiny surface could be achieved. The coating process in both scales can be considered as comparable with regard to moisture exposure to the cores during the coating process. The drying efficiency was kept in a similar range by only adjusting the inlet air quantity in large scale without changing the inlet air temperature. From the product quality point of view the resulting cores should therefore be equal regarding the stability towards moisture and temperature.

Solid wall coater

In these trials the football shaped caffeine tablets were used. The process settings for the GS HP 25 lab scale coater were determined as already described for the side vented pan coater. The process settings for the GS 300 were calculated based on these values (Table 4).

Compared to the trials in the side vented pan coating equipment, in this set of experiments the difference in batch size in small and large scale was distinctively higher. However, the calculated parameters for

	Optimal settings GS HP 25	Calculated settings GS 300
Batch size	22 kg	202 kg
Number of nozzles	1	4
Drum speed	8 rpm	4 rpm
Circumferential speed	335 mm/s	329 mm/s
Inlet air temperature	60 °C	60 °C
Inlet air quantity	350 m³/h	1,400 m³/h
Maximum spray rate	48 g/min	192 g/min

Table 4: Settings for the solid wall pan coating process.

the large scale coating process in the IMA GS 300 coater could be applied without the necessity of any changes. In both processes, the resulting tablets showed an equally smooth and shiny surface. Also for these trials, it can be assumed that both drying capacity and moisture exposure during the process were in the same range for both scales.

[2, 4]It had already been shown that the up scaling approach in side vented pan coaters is also applicable for other film coating formulations. However, one characteristic feature of the Perfima coaters is the availability of high inlet air volumes. Therefore, the coating process itself is less susceptible to over-wetting.

In solid wall processes, the air is exhausted via drying paddles located inside the core bed (Figure 1).

Figure 1: [5]Coating process in a solid wall coater.

Due to this set-up, lower air volumes are used in the film coating process. Therefore, one could assume that there is a higher risk for over-wetting especially during scale up. Yet the trials showed that this is not the case. The calculated parameters could be applied on the solid wall process, without showing any tendency of over-wetting.

Conclusion

Keeping the circumferential speed of the drum, the spray rate per nozzle and the ratio of process air volume per nozzles constant was an appropriate measure for scale up.

Taking into account all the results obtained in this study, the up scaling approach can be applied on both types of equipment – side vented as well as solid wall technology. This is of special importance for thermo labile and moisture sensitive formulations, as this kind of scale up assures that moisture and temperature exposure of the cores are kept as constant as possible. Hence, stability data gathered for cores coated in small scale are valid for tablets coated in large scale as well.

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