Influence of the Manufacturing Process on the Performance of Instant Release Coating Systems

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Objectives

Ready to use color coating systems are designed to reduce the production time for film coating tablets. These systems are composed of a film forming polymer, pigments and other additives. To prepare the coating suspension (figure 1), only the addition of water is needed. For easy handling, the product design should ensure excellent flowability, low dusting tendency, fast redispersion behavior without granule flotation or lump formation and avoid pigment segregation. Optimal particle design, therefore, is a prerequisite to guarantee optimal performance of the coating system.

The goal of this study was to investigate the effect each spray drying technique had on improving the preparation performance of the Kollicoat® IR coating suspension. For comparison, separate coating suspensions were spray dried and spray agglomerated. The resulting granules were characterized for powder properties and dissolution behavior.

Appearance of aqueous Kollicoat® IR suspension

Figure 1

Methods

The coating system Kollicoat® IR Yellow (BASF SE, Germany) was used for the experiments. For the spray drying experiments, an aqueous suspension of the coating system formulation was either spray dried or spray agglomerated.

The granules were characterized according to the Pharm. Eur. The bulk density, tapped density, flowability and angle of repose of the powders were all evaluated. Particle size was determined by laser diffraction (Malvern Mastersizer, Germany) and sieve analysis (10min, Retsch AS 200, Germany). The dusting tendency was analyzed with the Dust View technology (Palas GmbH, Germany). Dissolution time was investigated by dissolving 40 g of the granules in 160 g of water and visual inspection of the suspensions at different time intervals.

Results

Dry powder handling

The bulk density of the granules was not affected by the preparation method. However, a higher tapped density was observed for the spray dried product resulting in a Hausner ratio of 1.12, compared to 1.09 for the spray agglomerated product (see table 1). Due to the structure of the spray agglomerated product no segregation of fines occured under mechanical stress (see figure 2).

Effect of drying method on density and flowability

Drying method	Bulk density [g/ml]	Tapped density [g/ml]	Hausner Ratio	Flow time [sec]	Angle of repose [°]
Spray drying	0.32	0.36	1.12	11.9	26.4
Spray agglomeration	0.31	0.34	1.09	12.7	29.4

Table 1

Effect of spray drying method on particle morphology. Scanning electron microscopic picture of spray dried granules (above) and spray agglomerated product (below)

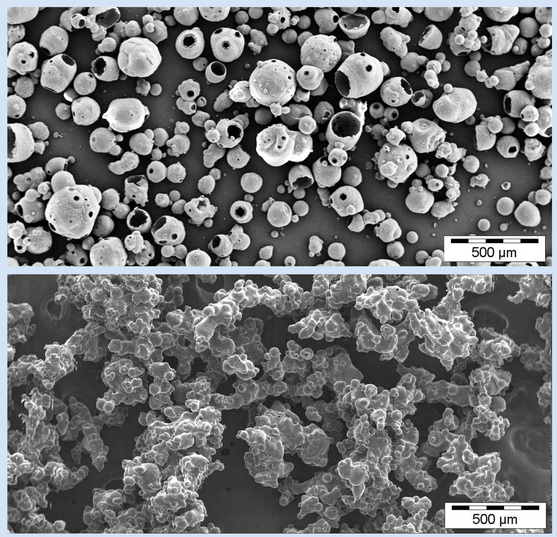

Figure 2

Investigating the particles size distributions of the granules, a minimal percentage of 2.19 % of finer particles below 200 µm was found for the agglomerated product in contrast to 47.5 % for the spray dried powder (see table 2 and figure 3).

These characteristics are reflected as well in the dust tendency of the powders. The spray agglomerated granules showed no dusting with a value as low as 3.4 ± 0.9 representing a dust free sample compared to 19.9 ± 3.5 for the spray dried powder.

Particle size distribution of spray dried (—) and spray agglomerated (—) product.

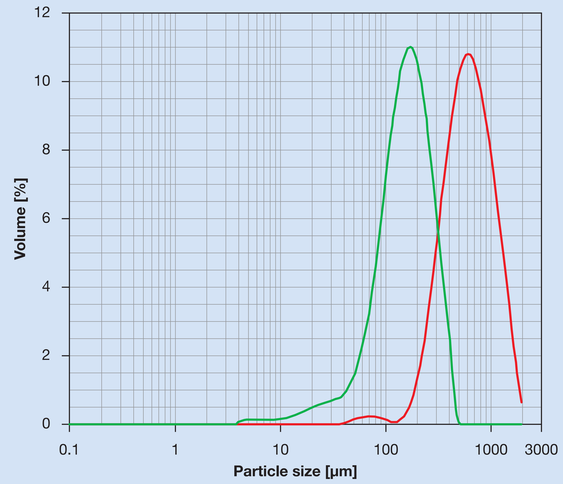

Figure 3

Particle size distribution of spray dried and spray agglomerated product determined by laser diffraction and by sieve analysis (*)

Product	d (0.1)	d (0.5)	d (0.9)	d (4.3)	< 500 µm*	< 200 µm	< 100 µm	> 300 µm
Spray dried	114.5	205.8	355.9	222	99.9 %*	47.5 %	5.6 %	19.7 %
Spray agglomerated	300.5	609.7	1207.3	688.8	41.4 %*	2.2 %	0.8 %	91.9 %

Table 2

Dissolution behavior

Both products dispersed easily in water without granule flotation or lump formation. However, when preparing the coating suspensions, the porous structure of the spray agglomerated product lead to a faster dissolution time. The porous structure of the spray agglomerated granules ensures easy water penetration. This avoids slowing of the dissolution by the formation of a concentrated polymer solution on the particle surface. The dissolution behavior is shown in figure 4.

Dissolution behaviour of colored coating systems exemplarily shown with Kollicoat® IR Brilliant Blue.

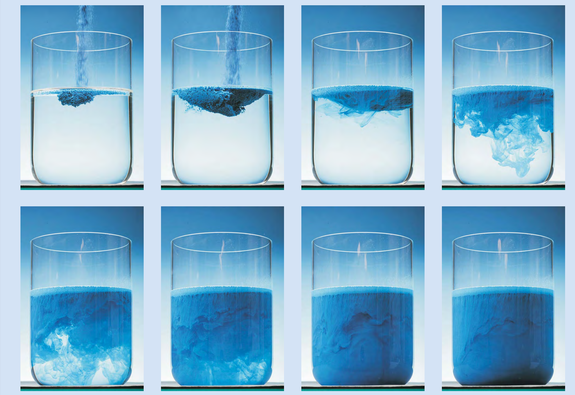

Figure 4

Conclusions

The spray agglomeration process is an optimal method for preparing instant release coating systems with minimal segregation and dusting tendency. The particle structure enables the preparation of a coating suspension in 15 min without the risk of lump formation.

Spray agglomeration was employed for the Kollicoat IR® Coating Systems because of the advantages of having:

- **a product with very low amount of fine particles without dust formation**
- **raspberry like particle structure ensures**
  - **– fast and easy redispersion in water without lump formation**
  - **– robust handling in production**
  - **– miscibility of different colors without particle segregation**

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