Investigating the Influence of Colouring Agents on the Rheological Characteristics of a Film-Coating Dispersion

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Purpose

Coating a tablet with a non-functional but coloured film is a standard procedure in the pharmaceutical industry. During the development and validation of such a film-coating process, a huge variety of data about the processability and applicability has to be gathered.

Hereby, the focus is typically set on the film forming polymer and its concentration which are known to have a strong impact on the coating result [1, 2]. However, further excipients are involved which might influence the processability as well.

The intention of this work was to investigate the influence of colouring agents on the rheological characteristics of a ready-to-use film coating system.

Materials and Methods

Materials

The polymers Kollicoat® IR and Kollidon® VA64 as well as the ready-to-use coatings Kollicoat® IR White II, Kollicoat® IR Sunset Yellow, Kollicoat® IR Carmine and Kollicoat® IR Red (all BASF SE, Ludwigshafen, Germany) were used.

All ready-to-use formulations contain Kollicoat® IR and Kollidon® VA64 as film-formers and the pigments kaolin and titanium dioxide. The individual colours are obtained by adding either an aluminium lake (sunset yellow, carmine) or an iron oxide (red) to the formulation.

Methods

Aqueous dispersions of these products were prepared in different concentrations to determine their individual rheological characteristics.

Extensional viscosity

For extensional testing, the Thermo Scientific HAAKE CaBER 1 (Thermo Fisher Scientific, Karlsruhe, Germany) was used. This equipment determines the capillary break-up time (filament life-time) as a measure for the extensional viscosity.

Dynamic shear viscosity

In order to measure the dynamic shear viscosity, the Thermo Scientific HAAKE RotoVisco 1 rotational rheometer (Thermo Fisher Scientific, Karlsruhe, Germany) with liquid temperature control for concentric cylinder measuring geometries was used.

Results and Discussion

When optimising a film-coating process in regard to efficiency, the shortest possible time for applying the required weight gain homogenously onto the cores has to be determined. The main influencing parameters are spray rate and solid matter content of the film-coating dispersion, whereas an increase of one of these parameters already leads to a shorter processing time.

By varying the inlet air temperature (50, 60, 70 °C) and spray rate, the shortest total spraying time for different solid matter contents was determined (Figure 1). It was found that the spraying dispersion holding 30 % solids showed distinctively different coating properties resulting in lower possible spray rates. This could be explained by a decisive change of the dispersions' viscosity. It was suggested that the results could only be transferred to formulations showing the same rheological characteristics [3].

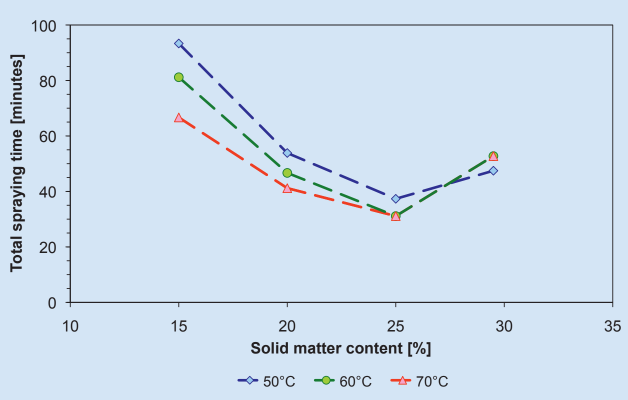

Figure 1: Determination of the optimal solid matter content for a film-coating process resulting in the shortest possible spraying time (Kollicoat® IR Carmine) at three different inlet air temperatures [3]

Dynamic shear viscosity

Dynamic shear viscosity is an indicator for the spreading behaviour of the droplets on the core surface. Hence, this value is to be used for estimating the final coat quality in regard to smoothness.

All formulations showed a shear viscosity clearly depending on solid matter content (Figure 2). However, there was hardly any difference between the dispersions up to a concentration of 25 %. At 30 % and especially 35 %, the flow properties differed markedly. The highest increase was found for Kollicoat® IR Sunset Yellow. The second ready-to-use coating containing an aluminium lake (Kollicoat® IR Carmine), yielded a low increase in shear viscosity. Interestingly, Kollicoat® IR Carmine and Kollicoat® IR Red (which holds an iron oxide) were found with the same viscosity curves.

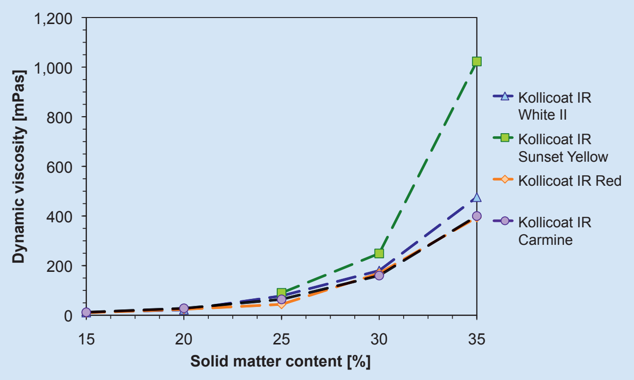

Figure 2: Dynamic shear viscosity of different Kollicoat® IR based film-coating dispersions as function of solid matter content measured at 25 °C

Extensional viscosity

Extensional viscosity is an indicator for droplet formation as well as for the risk of spray drying. In a first test, the general effect of pigments on the extensional parameter filament life-time (FLT) was investigated. In order to do this, Kollicoat® IR White II dispersions (25, 30, 35 %) were compared to polymer solutions containing Kollicoat® IR and Kollidon® VA64 in exactly the ratio and quantity as they are present in the dispersion (16.6, 19.9, 23.2 %).

At 25 % solids, there was hardly any difference between the polymer solution and Kollicoat® IR White II dispersion (Figure 3). Increasing the solid matter content resulted in a longer FLT for both formulations. However, the pigments present in Kollicoat® IR White II pronounced this effect leading to longer FLTs for the dispersion compared to the equivalent polymer solution.

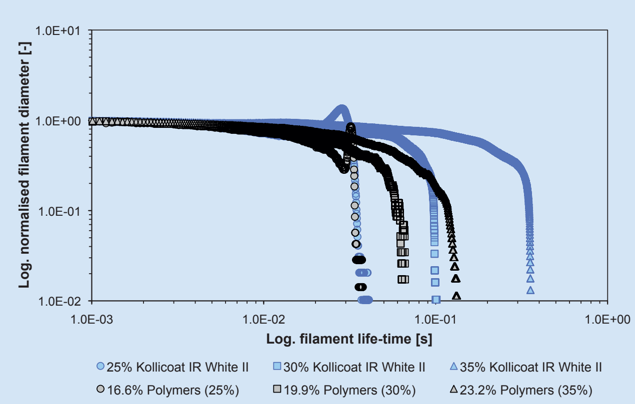

Figure 3: Filament life-time of polymer solutions in comparison to dispersions of Kollicoat® IR White II

After considering the general effects of pigments on FLT, the impact of different colorants was investigated in a second set of experiments (Figure 4). When comparing the three different colours White II, Sunset Yellow and Red a similar FLT could be found for solid matter contents of 25 %. However, at higher concentrations markedly different FLTs were found for the different formulations. This suggests that surface effects caused by the individual colorants affected the rheological properties of the spraying dispersion at higher solid matter contents.

Both investigations (shear and extensional viscosity) showed that the colouring agents did not influence the rheological properties at solid matter contents of 25 %. As soon as the solid matter content was increased to 30 % or above, a pronounced effect of the colorant was observed. This suggests that coating parameters can be transferred from one formulation to another for spraying dispersion not higher concentrated than 25 %.

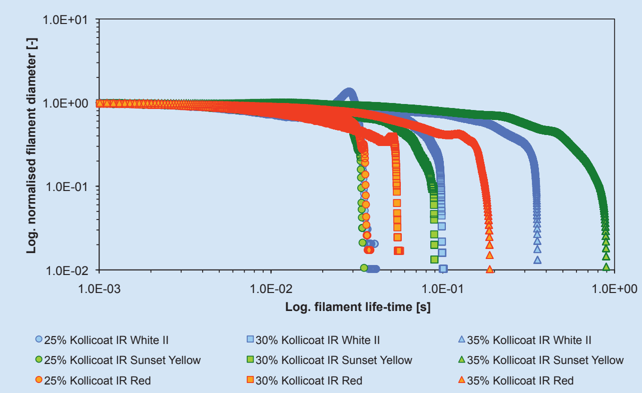

Figure 4: Filament life-time of different Kollicoat® IR based film-coating dispersions holding different colorants as function of solid matter content

Conclusion

Dynamic and extensional viscosity were found to be dependent on the solid matter content of the spraying dispersion. As soon as a concentration of 25 % was exceeded the colouring agent had a distinctive influence on both rheological characteristics.

This suggested that coating parameters can be used universally and independently of the colorant as long as the basic formulation (in regard to the kind and amount of polymers) is equivalent and a solid matter content of 25 % is not exceeded. In regard to higher concentrations, the pigments influence the coating properties and parameters have to be gathered separately for each individual colour.

References

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