Benchmarking the coating properties of Kollicoat® IR with alternative film-formers used for instant release film-coating

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INTRODUCTION

Nowadays, polymers such as poly(ethylene glycol)-poly(vinyl alcohol) graft copolymer [Kollicoat® IR], poly(vinyl alcohol) [PVA] and hydroxypropyl methylcellulose [HPMC] are stand film-formers in instant release coating formulations. Physical properties of these polymers (e.g. viscosity, plasticity, film-forming characteristics, etc.) differ distinctively, though. Yet, these differences have a great impact on the coating parameters and the processing characteristics in general.

The respective polymer-specific characteristics determine the para-meters which have to be applied to run the film-coating process reliably and reproducibly. Therefore, polymers which are applicable in a broad range of process settings are of special benefit.

OBJECTIVE

As the film-coating process depends on a wide range of parameters it is challenging to compare the coating characteristics of different film-formers.

The aim of this work was the comparison of the individual coating properties of the polymers investigated: Kollicoat® IR, PVA, HPMC 3 and HPMC 6 mPas [1].

This can be achieved by employing a so-called Process-Parameter-Chart [2]. The chart displays in a clear and easy way the surface quality of the coated tablets as a function of product temperature and process time at standardised settings (Table 3).

MATERIALS AND METHODS

The viscosity of the polymer solution has a strong impact on the processing parameters [1]. To allow a proper comparison, the individual polymer concentration leading to a dynamic viscosity value of 50 mPas was chosen (Table 1). Placebo cores of low friability were used in the tests (Table 2).

Table 1.
Polymer contents of the aqueous solutions investigated.

Polymer	Solid content
Kollicoat® IR	17.0%
HPMC 3 mPas	10.0%
HPMC 6 mPas	6.0%
PVA	11.0%

Table 2.
Composition of the tablet cores

Excipient	Content
Ludipress® LCE	224.0 mg
Kollidon® VA 64	53.9 mg
Magnesium stearate	2.1 mg
Total tablet weight	280.0 mg

A Manesty AccelaCota 24” equipped with rabbit ear baffles and a Schlick ABC nozzle (orifice: 1.0 mm) was employed for this investigation.

Apart from the properties of the spraying solution, the coating process depends on the five main parameters:

inlet air quantity, inlet air temperature, spray rate, batch size and weight gain. Standardising the settings listed in Table 3 the remaining variables of the coating process are spray rate and product temperature.

Table 3.
Standardised setting for this investigation.

Parameter	Setting
Batch size	8,500 g
Weight gain	3.5%
Drum speed	12 rpm
Exhaust air quantity	410 m³/h
Atomising air pressure	2.0 bar
Flat jet air pressure	1.0 bar

The process time displayed in the final chart was calculated according to Equation 1.

Equation 1.
Calculation of total spraying time.

$$\frac{\text{core mass [g] x weight gain}}{\text{spray rate}\left[\frac{\text{g}}{\text{min}}\right] \text{ x solid matter content}} = \text{process time}$$

According to the surface quality the coated tablets were classified into four categories as explained in Table 4.

Table 4.
Classification system to appraise the coating process' quality.

Class 1	Film-coating process is not possible; sticking due to over-wetting is observed.
Class 2	Film-coating process is possible, but the coated surface of the tablets is not acceptable.
Class 3	Film-coating process is possible, the coated surface of the tablets is acceptable.
Class 4	Film-coating process is possible, the coated surface of the tablets is optimal.

RESULTS AND DISCUSSION

HPMC 3 mPas (Figure 1) showed the typical characteristics of a brittle film former. Exceeding a product temperature of about 42°C the formed film showed defects due to mechanical stress. At lower product temperatures of about 25 to 30°C (depending on the process time) sticking was observed. Therefore, good results could be achieved only in a narrow parameter range.

In contrast to the 3 mPas grade the HPMC 6 mPas (Figure 2) showed no brittleness at elevated temperatures. At any rate, the transition from a well running process to primary sticking effects was very quick. Therefore, processes with this polymer are very difficult to handle. In addition, the decidedly lower solid content of the spraying solution results in a remarkably longer process time.

PVA (Figure 3) is a sticky film-former in a wetted state. Therefore, good results could only be achieved with very dry coating conditions minimizing the plasticising effect of water.

Kollicoat® IR (Figure 4) showed by far the best coating properties. The coating process could be performed in a very broad range of parameters. Depending on the spray rate even at product temperatures of 15°C coating was possible.

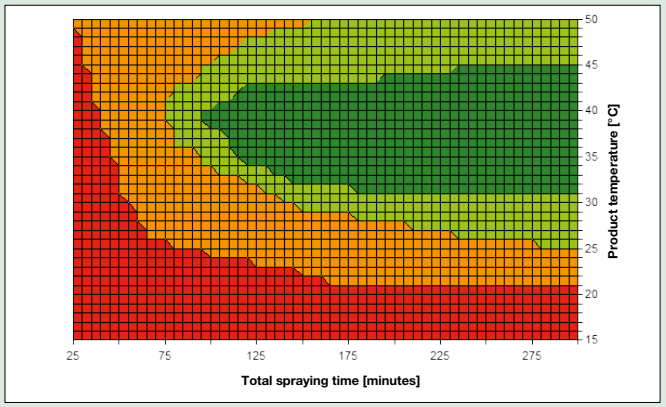

Figure 1.
Process-Parameter-Chart of HPMC 3 mPas.

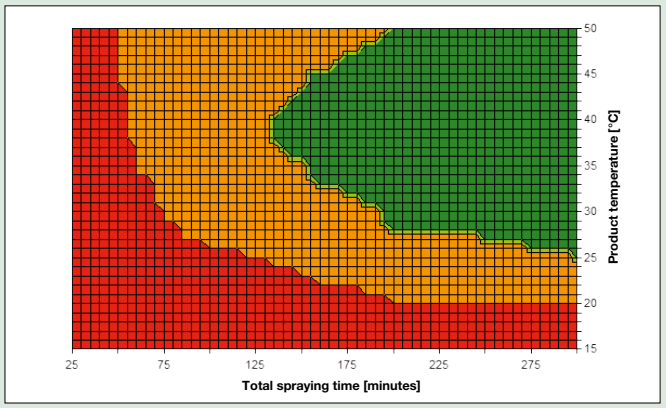

Figure 2.
Process-Parameter-Chart of HPMC 6 mPas.

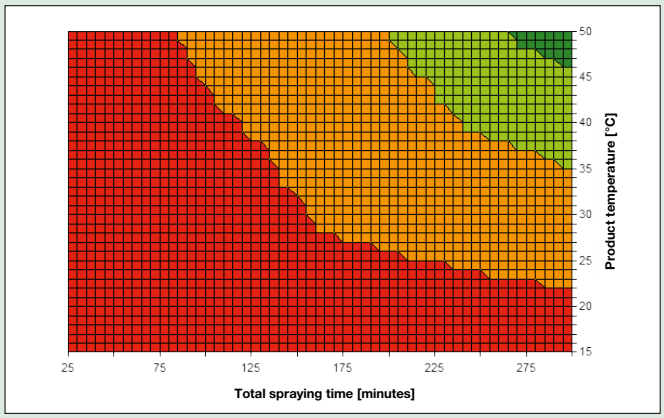

Figure 3.
Process-Parameter-Chart of PVA.

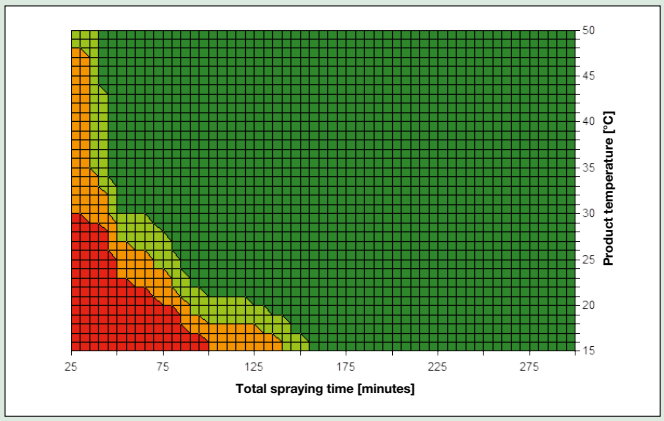

Figure 4.
Process-Parameter-Chart of Kollicoat® IR.

CONCLUSION

Due to its low viscosity, polymer content of the Kollicoat® IR solution was highest. Therefore, shortest process times could be achieved with this product.

Kollicoat® IR and HPMC 6 mPas can be used as single polymers for film-coating. PVA as well as HPMC 3 mPas have to be mixed with additives to improve the coating properties.

Despite the general coatability HPMC 6 mPas should also be mixed with a second film-former to decrease viscosity.

Kollicoat® IR is the only polymer to make coating possible below ambient temperature.

Kollicoat® IR needs to be mixed with colorants only to formulate the final spraying dispersion.

REFERENCES

[1.] Th. Cech: Benchmarking of Instant Release Film Coating Polymers; Bachelor Thesis.

[2.] Th. Cech, K. Kolter, Comparison of the Coating Properties of Instant Release Film Coating Materials Using a Newly Developed Test Method – the Process-Parameter-Chart, PSWC 2007

Presented at:
Aurora Film-Coating Symposium, May 15, 2018; Kiev, Ukraine
Pharma Solutions Europe | G-ENP/ET544

Kollicoat® IR

The true multitalent

- Water-soluble film former for instant release coatings
- High pigment-loading capacity
- Excellent wet binder
- Easy processing due to low solution viscosity and very fast dissolution
- No peroxide formation

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