# Using different coating technologies to apply a Kollicoat® Smartseal 30 based functional coat onto drug layered pellets

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## Introduction

One has to consider various aspects when deciding on a coating technology. Process efficiency, content uniformity of the applied coat, and economical aspects are features of utmost importance, yet vary depending on the type of coating to be employed, especially within the realm of functional coating and/or drug layering, this question is of serious importance.

## Aim

The aim of this study was to compare three different coating technologies efficiency in a pellet coating process.

## Materials and methods

Pellets (20 – 25 mesh, Emilio Castelli) consisting of sucrose and microcrystalline cellulose were used as substrate. As tracer, riboflavin (BASF) embedded in a film of poly(vinyl alcohol)-poly(ethylene glycol) graft copolymer (Kollicoat® IR, BASF), ratio 1:2, was applied as aqueous formulation with a solid matter content of 15%.

The functional coat was based on poly(methyl methacrylate-co-(2-diethylaminoethyl) methacrylate) copolymer (Kollicoat® Smartseal 30 D, BASF) [1]. Further components of the formulation (Table 1) were: FD&C Blue No. 1 (BASF), acetyl tributyl citrate (ATBC, Jungbunzlauer), buthylene hydroxy toluene (BHT, Lanxess), docusate sodium (DS, Cytec), and talc (Merck). The solid matter content of the formulated Kollicoat® Smartseal dispersion was 20%.

Three different coating technologies were used in this study: a fluid bed coater (FBC) Ghibli Lab (Figure 1), with bottom spray configuration, a solid wall drum coater (SWC) GS Evolution Lab (Figure 2), and a side vented pan coater (SVP) Perfima Lab (Figure 3), with slot drum. The latter equipment held a drum specifically designed for coating of small substrates such as pellets. Small slots are worked into the drum wall to allow the passage of process air. The drum maintained the same drum shape, mixing baffles and spray system as the standard equipment for tablet coating. All machines were provided by IMA (Bologna). The coating trials were performed according to schema listed in Table 2.

To allow a distinct investigation on the coating level, the individual amount of applied coat was determined by photometrical measuring of either riboflavin or the colorant FD&C Blue No. 1 [2, 3].

For dissolution testing, a standard USP Dissolution Apparatus 2 (Paddle) from ERWEKA, equipped with continuous on-line UV measuring (Agilent 8453), was used. Since taste-masking functionality is to be delivered in the oral cavity, phosphate buffer (pH 6.8) was used as dissolution media (700 mL ±1%, 37°C ±0.5 K, n=13).

**Table 1. Coating formulation for the functional coat.**

| Ingredient | Content | Polymer based |
|---|---|---|
| Kollicoat® Smartseal 30 D | 50.5% | |
| Acetyl tributyl citrate (ATBC) | 7.6% | 15.0% |
| Buthylene hydroxy toluene (BHT) | 1.3% | 2.5% |
| Docusate sodium (DS) | 1.0% | 2.0% |
| Talc | 39.0% | |
| FD&C Blue No. 1 | 1.0% | |

**Table 2. Parameter set for the different processes.**

| Parameter | Fluid bed coater (FBC) | Solid wall coater (SWC) | Side vented pan coater (SVP) |
|---|---|---|---|
| Batch size | 2.5 kg | 25 kg | 25 kg |
| Batch volume | 3.0 L | 30 L | 30 L |
| Inlet air temperature | 55 – 68°C | 65 – 70°C | 75 – 80°C |
| Air quantity | 140 – 170 m³/h | 500 m³/h | 600 m³/h |
| Orifice diameter | 1.2 mm | 1.2 mm | 1.2 mm |
| Spray rate | 25 mL/min | 25 – 30 mL/min | 50 – 70 mL/min |
| Atomisation air pressure | 1.2 bar | 1.2 bar | 1.2 bar |


**Figure 1. Fluid bed coater (FBC), Ghibli Lab.**


**Figure 2. Solid wall drum coater (SWC), GS Evolution Lab.**


**Figure 3. Side vented pan coater (SVP), Perfima Lab.**

## Results and discussion

Firstly, riboflavin was coated onto the pellets as a tracer for the performance testing of the functional coat (dissolution). In all three coaters, the same coating formulation with the same solid matter content was sprayed onto the pellets for five hours, using optimised settings for each individual technology. The achieved weight gain revealed an excellent performance of the fluid bed coater. However, employing standard deviation as a scale for content uniformity, the solid wall coater presented best results due to longer processing times required (Table 3).

**Table 3. Overview of weight gain and coating uniformity, conditional of manufacturing (equipment dependent).**

| Coater | Weight gain | Standard deviation |
|---|---|---|
| Fluid bed coater (FBC) | 6.02% | 3.62% |
| Solid wall coater (SWC) | 3.38% | 2.43% |
| Side vented pan coater (SCP) | 4.84% | 3.87% |

The coating formulation used typically needs to be applied with a coating level of 3.5 mg/cm² onto tablets to gain functionality [4]. When applying the same coating formulation, onto pellets, full functionality could be achieved with distinctively lower coating levels in all coaters. The reason was, most likely, the absence of the critical edge between band and cap, which every tablet bears inherently. Pellets with their spherical shape do not offer such crucial areas.

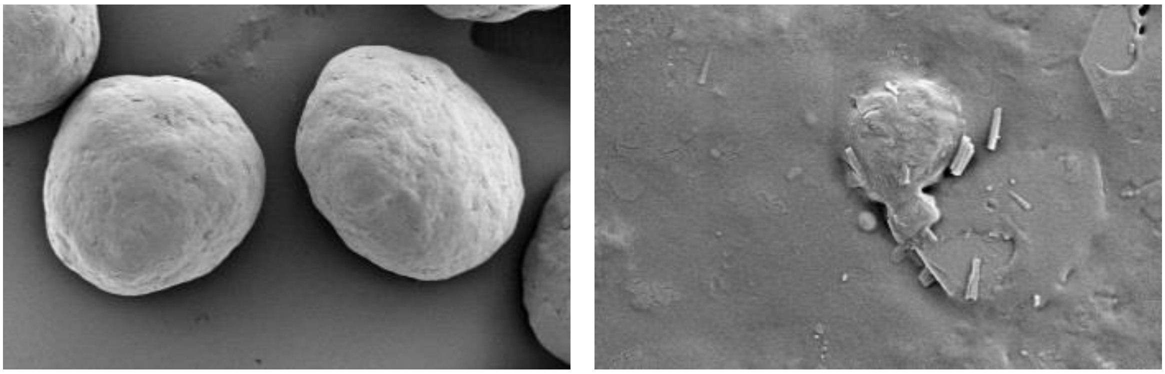

**Figure 4. SEM images (different resolution) of pellets coated in fluid bed coater (SE detector, 5 kV, 12 nm Pt).**

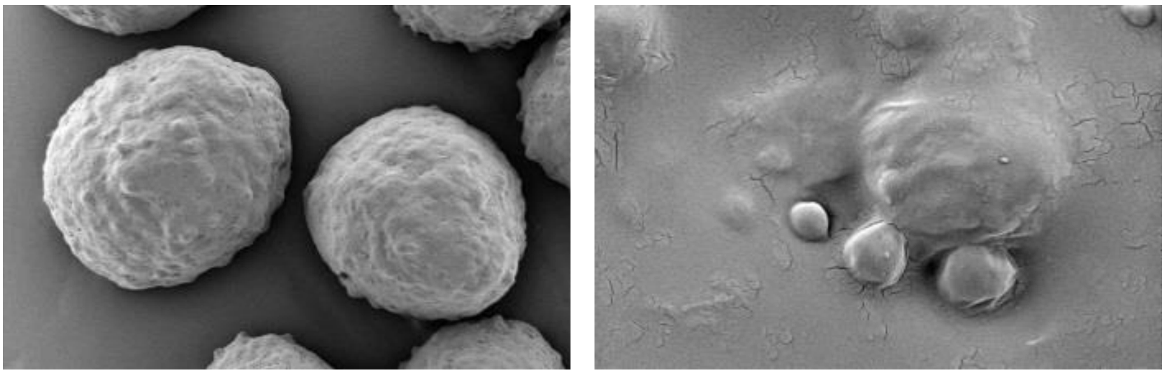

**Figure 5. SEM images (different resolution) of pellets coated in solid wall coater (SE detector, 5 kV, 12 nm Pt).**

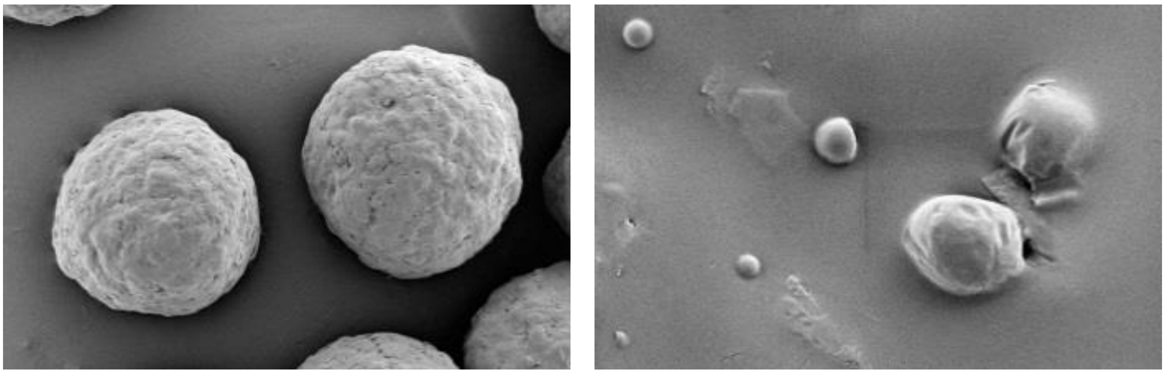

**Figure 6. SEM images (different resolution) of pellets coated in side vented pan coater (SE detector, 5 kV, 12 nm Pt).**

Pellets, which passed through a fluid bed coating process experienced hardly any mechanical stress. In addition, to the cushioning effect provided by the processing air, the excellent accessibility of the whole product's surface area allowed perfect drying. This produces coated substrates, with smooth surfaces (Figure 4), already delivering functionality at moderate coating levels (Figure 7). The mechanical impact on the substrate was higher in both drum coaters leading to the surfaces appearing slightly rougher (Figure 5, Figure 6). Functionality was achieved at similar coating levels in both coaters. Differences were merely found regarding processing time, due to differences in the available inlet air quantities.

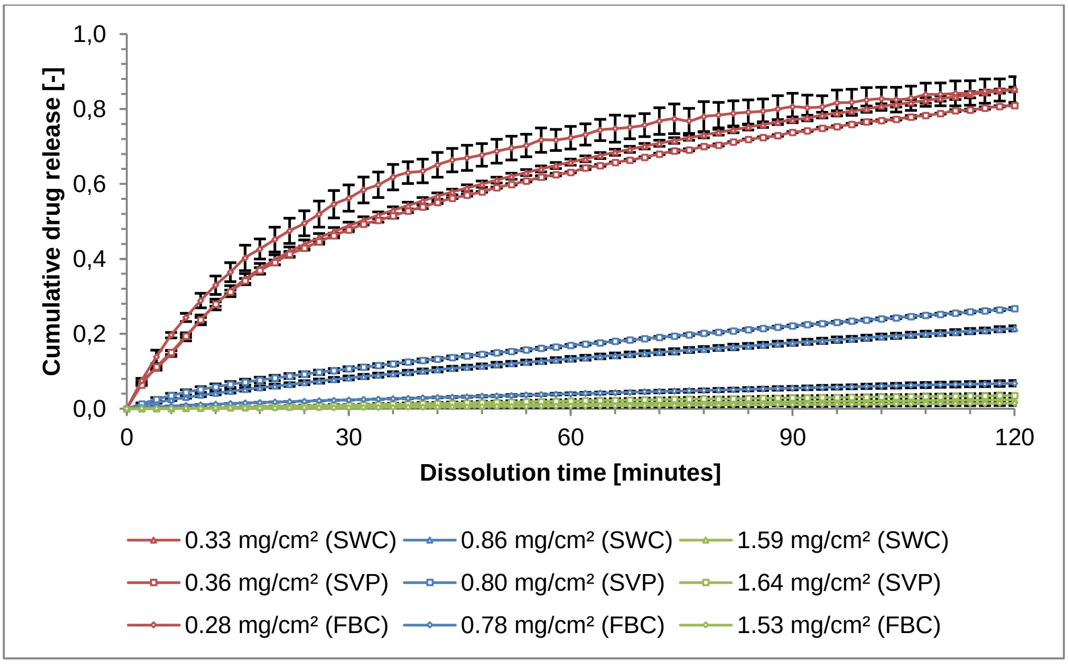


**Figure 7. Dissolution profiles of pellets bearing three different functional coating levels applied in different coating technologies (values: mean ±SD, n=3).**

## Conclusion

Fluid bed coating allowed the shortest possible processing times. Due to it, inherently providing high drying and mixing efficiency, so that coating formulations could be applied quicker and more homogeneously.

In contrast, both pan coaters offer the advantage of being a more compact installation. Larger batch sizes could be coated in smaller and more easily accessible machinery. In turn, one needs to accept some mechanical stress for the substrates calling for slightly higher coating levels.

Side vented pan coating allowed high inlet air quantities resulting in higher spray rates. Solid wall coating generally allows a vast variety of different processes (e.g. tablet coating, powder layering). In order to gain this flexibility, one needs to sacrifice on the amount of inlet air that can be utilised. As a result, processing times were slightly longer but offer the advantage of gaining a higher coating uniformity.

## References


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## Keywords

Kollicoat® Smartseal 30 D, film-coating, taste masking, pellets, drug-layering


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