

# Polyvinyl Alcohol (PVA) for Tablet Coating Applications: Enhancing Formulation Flexibility

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## Purpose

Polyvinyl alcohol (PVA) is a synthetic, bio-compatible and toxicologically well-characterized polymer that is well-established for film coating. It is frequently used in pre-mixed coating formulations. Fixed combinations with additional ingredients are also well-established. The performance of the coating can be further optimized during individual formulation development. The properties of the polymeric films can be influenced and finetuned according to requirements. However, techniques for characterizing film-coated tablets are quite limited. As such, it is of interest to develop a reliable characterization technique for coated tablets that can be easily implemented in early formulation development.

## Objective

The main objective is to establish a flexible formulation platform for PVA-based coatings. The idea is to apply novel analytical technologies to improve the performance of the coating system in early stages of development.

## Methods

### 3D laser scanning confocal microscopy

As an initial step, a stack of different optical images is captured by a confocal microscope for the purposes of calculating a sharp image of the surface. In the second step, a laser scans the surface of the sample and detects the light intensity for every surface point. The light intensity of the reflected laser light as a function of the vertical position of the sample is used to calculate the z-value of each surface point. Confocal Laser Scanning Microscope: Keyence VK-X210.

### Coating conditions and core tablets

Coating was performed using an LDCS-type rotating drum coater from Freund-Vector. Plasticizers were compared at 10% and 30: Triethyl citrate, glycerol, triacetin, and two different sugar alcohols – sorbitol and mannitol. The targeted weight gain was set to 3%. The core tablets consisted of 98.5% mannitol + 1.5% magnesium stearate.

## Results

### Evaluation of surface roughness

The roughness of the tablets depends on the selected measurement region. It is expected that the greater the distance to the center of the tablet, the greater the roughness. The measurement regions for characterizing the roughness close to the edge of the tablet must be well-defined. A dedicated laser scanning microscopy method (LSM) was used to evaluate the surface structure of the various film coatings. A defined raster was established to provide reliable information on the tablet surface and to evaluate the surface roughness at defined regions (center and edge regions). A schematic view of the surface areas is presented in Figure 1. Direct topographic data from the LSM scan is presented in Figure 2.

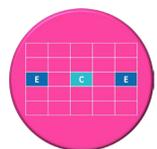


Figure 1: Schematic view of the measured regions on the tablet surface used for LSM scanning; C: Center region, M: Edge region.

The analytical results for the tablet surface roughness are presented in Figure 3 and Figure 4. For the evaluated formulations, the surface roughness is rather consistent in all measurement regions. Particularly for triethyl citrate, triacetin and mannitol, high concentration formulations show a positive impact on the reduction of coating surface roughness. The addition of sorbitol is also seen to have positive effects on the tablet surface. At higher concentrations (30%), the finishing of the tablets is improved even further. For glycerol, almost no changes in surface roughness were observed regardless of the concentration used. SEM images of the coated tablet surfaces are presented in Figure 5 for comparison purposes.

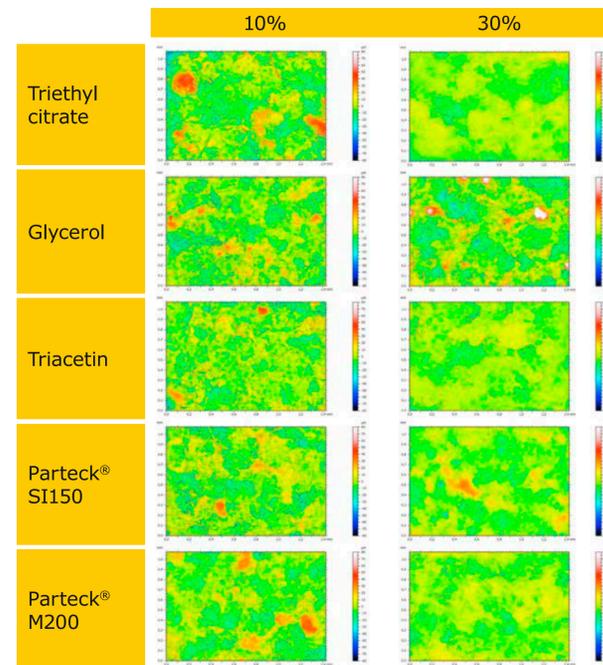


Figure 2: Sample topographic LSM images of the coated tablet surfaces; central regions.

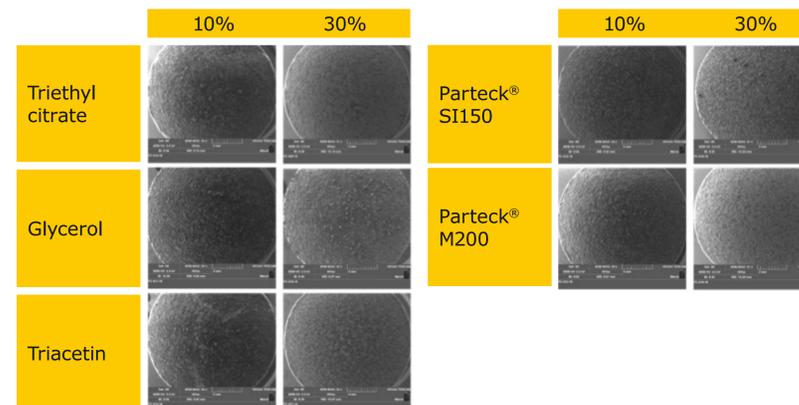


Figure 5: SEM images of coated tablet surfaces with different plasticizers at varying target concentrations. (10% and 30%).

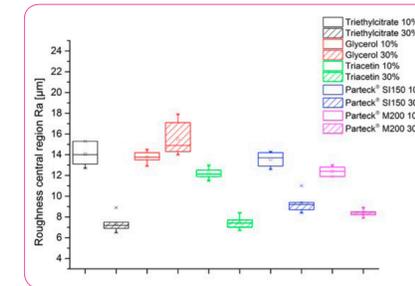


Figure 3: Box plots representing the surface roughness (Ra) of the film-coated tablets (central region; n = 6).

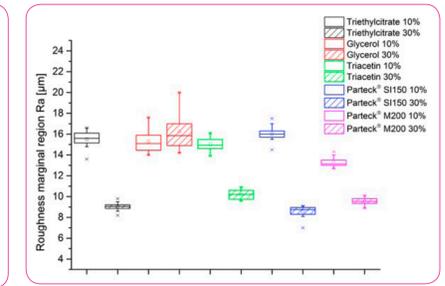


Figure 4: Box plots representing the surface roughness (Ra) of the film-coated tablets (edge region; n = 12).

## Conclusions

Film coating processes are often not yet fully understood, which presents a regulatory challenge. Novel analytical technologies and modeling approaches are used to increase the understanding of film coating processes.<sup>1</sup>

The newly established laser scanning method provides an important tool for formulation development and enables a thorough characterization and understanding of the film surface.

The impact of different plasticizers on the homogeneity of the coated tablet surfaces was successfully evaluated for polyvinyl alcohol-based coatings.

In addition to common plasticizers like triethyl citrate or triacetin, the use of polyols such as mannitol and sorbitol can be of great interest when it comes to improving the surface finishing of PVA-based coatings.

For the evaluated setup, surface roughness was relatively independent of the measurement position, which indicates consistent film strength across the entire tablet surface.

Understanding the impact of the formulation on coating processes and final surface finishing in early stages of development can be an important driver for successful development.

Generating comprehensive formulation knowledge is also an essential step when embarking on novel technological approaches such as continuous coating processes.

## References

1. Felton LA, Porter SC. An update on pharmaceutical film coating for drug delivery. Expert Opinion on Drug Delivery. 2013;10(4):421–35.

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