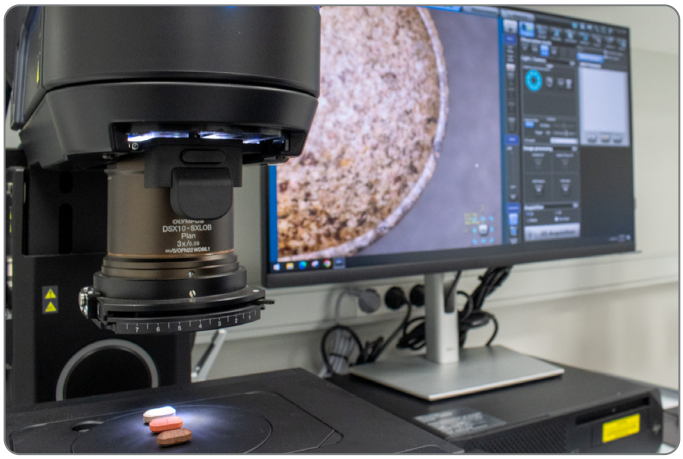
Overcoming the Challenges of Coating Moisture-Sensitive Formulations Case Study

Tablet coating is a fundamental process in the pharmaceutical industry that ensures the stability, bioavailability, and aesthetic appeal of medications. This is quite challenging to achieve, especially when a formulation is sensitive to moisture.

In this case study, we faced a client whose tablet formulation exhibited high sensitivity to moisture. Exposure to humidity caused the appearance of black spots and a lack of uniformity in the coating, compromising the quality of the final product and patient satisfaction.

Romaco Tecpharm proposed a customized solution using the **TPR OPT** coating technology. Thanks to the precision and versatility of this machine, we were able to overcome the challenges and give a uniform and good-quality coating to meet the demanding requirements of the client.



The Challenge

The client's tablet formulation exhibited high sensitivity to moisture. Upon contact with water, the tablet components reacted, generating black spots that significantly affected the product's appearance. Additionally, the lack of uniformity in the coating compromised the quality and controlled release of the active ingredient.

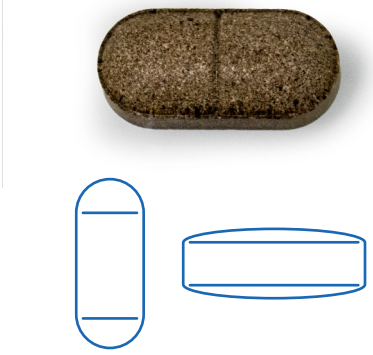
To achieve adequate coating, it was necessary to work under very specific conditions. Temperature, airflow, and other process parameters had to be adjusted precisely to prevent moisture condensation and ensure a uniform coating application. However, finding the optimal combination of parameters was complex and required a highly precise and versatile coating machine.

About the product

Nutraceutical, specifically vitamin supplements.

Coating agent	
Description of the components:	hydroxypropyl methyl cellulose; starch; magnesium carbonates; hydroxypropyl cellulose; medium chain triglicerides; iron oxides and hydroxides; carminic acid
Solvent	Water
Content of solids	17%

Purpose and description of the trial	
Batch size	200Kg
Weight gain	3%



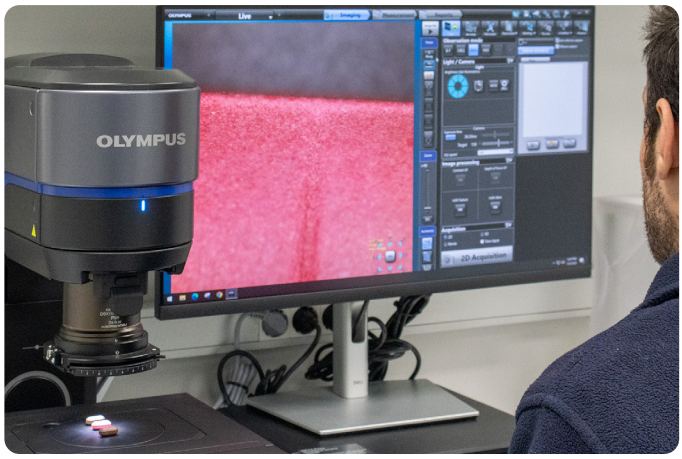
Tablet shape

Our Solution: The Precision of the TPR OPT

By analyzing the tablet formulation, we identified the critical parameters that needed to be adjusted to prevent the formation of spots and ensure a uniform coating. The most relevant parameters include:

- **Bed temperature:** The bed temperature was adjusted to keep the tablets dry and prevent moisture condensation.
- **Airflow and humidity control**: The airflow was adjusted to reduce the absolute humidity at the air inlet of the equipment, increasing drying efficiency.
- **Drum rotation speed**: The drum rotation speed was adjusted to ensure a uniform distribution of the coating on the tablet surface.
- **Preheating**: A homogeneous preheating was used thanks to custom deflectors, eliminating much of the residual moisture within the tablet.
- **Spraying**: The spraying parameters were adjusted to achieve perfect spraying, minimizing the amount of aqueous solvent reaching the tablet.

The versatility of the **TPR OPT** allowed us to make precise adjustments to all these parameters, which was essential to achieving a high-quality coating.



Microscopic view of a tablet demonstrating optimal coating parameters.

Repeatability and Robustness

After several tests and adjustments, the optimal parameters were defined to create an automatic recipe. This recipe guarantees the repeatability and robustness of the process, providing the client with the assurance of obtaining a high-quality product in each batch

Conclusions

This case study demonstrates the importance of having precise and versatile coating technology to overcome the challenges associated with sensitive formulations. The **TPR OPT**, thanks to its adaptability and precise control of process parameters, allowed us to find the optimal solution for this client. The results obtained demonstrate that investing in cutting-edge technology is essential to ensuring quality and efficiency in the production of medications.