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API – excipient interactions in solid matrix systems

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Solid dosage forms are still the most preferred types of medicines in the pharmaceutical market. Due to the emerging trend on personalized medicine, the pharmaceutical industry faces a new challenge on providing matrix systems with tailorable properties. To fulfil this request, a novel approach of pharmaceutical design may be applied with a more detailed investigation of physico-chemical property-based interactions between the drug and the applied excipients. The main aim of this research work is the better understanding of these interactions and fulfilling the requirements of the 'Functionality related properties of materials' concept of Quality by Design.

A line of chemically similar APIs and matrix forming agents were mixed and directly compressed with an instrumented IMA Kilian SP300 tablet press. The interactions formed within the tablets were studied by FT-IR and NIR spectroscopy, and a custom-made device was used to perform dissolution tests to obtain information about the effects of interactions on the drug liberation kinetics.

The spectral information revealed that hydrogen bonds are formed between the drug and excipients even in solid state, while investigations during dissolution tests proved that the strength of interactions increased due to the formation of polyelectrolyte complexes, which affects not just the speed of drug liberation but also the quantity of the liberated drug.

According to the findings it can be concluded that in addition to the physico-chemical properties of the drug delivery system, drug liberation is considerably influenced by the chemical interactions formed between APIs and excipients.

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