Validation of Tablet Coding Parameters

Tablet coating is widely used in the pharmaceutical industry to provide tablets with a functional thin film. The purposes of the film include the resistance to gastric juice and the control of the release rate of the active pharmaceutical ingredient (API). The process of tablet coating is complex due to the fact that many inter-dependent parameters take influence on the quality of the final product. In this work, a Design of Experiments (DoE) plan was created to produce tablet batches with three coating process parameters that were Out of Specification (OOS). The coating thickness was determined with a µm-caliper and with Optical Coherence Tomography (OCT). Those results served as a reference for the implementation of Multivariate Data Analysis (MVDA) models that are able to predict the coating thickness of tablets from recorded Near-Infrared (NIR) or Raman spectra. The applied methods were compared regarding their potential to serve as a Process Analytical Technology (PAT) tool. As the last step, the same tablets were investigated in the destructive USP II dissolution test to get information on gastric juice resistance and API release characteristics. Those attributes are the critical quality attributes and decide whether a produced batch goes on sale or not. The obtained results were analyzed, the influence of process parameters on the dissolution test result was validated and a better process comprehension was gained.