

P-027: Process Analytical Technology (PAT) for Quality by Design focused process development and water based extraction techniques for the isolation of valuable components from naturally variable raw material

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Objectives

Plant metabolites are an important group of compounds with applications in medicine, crop protection and focus of extensive research. The isolation of these compounds from plants with natural variability is complex and requires robust, and economically feasible processes. The objective is the development of extraction and purification processes with minimal use of organic solvents, which guarantee optimal product quality and include modern quality control strategies, while maintaining economic efficiency. Further,

Methods

The Quality-by-Design focused approach to process development combines statistical design of experiments and rigorous process models in order to characterize the impact of raw material properties on product quality. The significance of different materials and process parameters is evaluated and implemented into process models. Alternative solvents and process chains are evaluated in order to achieve the most resource efficient process. In the next step, PAT is employed to monitor quality attributes.

Results

The different steps of Quality-by-Design focused approach to process development are shown on different examples. Additionally, studies utilizing rigorous process models show the optimization potential of the extraction processes and their advantage over a purely experimental study or statistical models. The influence of different process parameters and raw material properties, such as solvent composition, temperature or particle size on the extraction performance is demonstrated. Finally, different applications of process analytical technologies and other quality control strategies are shown, which allow real-time monitoring of relevant quality attributes.