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Speeding Up Pharmaceutical U-HPLC Method Development with an Integrated, Ultrafast Automated Method Scouting Solution

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HPLC method development is still considered to be one of the crucial bottlenecks that impede productivity in analytical laboratories. Due to the variety of available columns, the proper selection of the stationary phase usually represents the greatest challenge. With the progress in U-HPLC which enables generic gradient separations within 5 minutes or less, ultrafast method development techniques become possible. While conventional LC rarely supported more than one generic gradient run per hour, U-HPLC can do a multitude of chromatographic runs in the same amount of time. This allows changing the experimental approach from thoroughly designing a small number of initial experiments towards a more comprehensive screening along any possible combination of column/eluent/temperature. Thanks to the very short run times of U-HPLC, this can be accomplished within the same time frame as the conventional approach. However this screening provides a significantly broader set of results, more information on the influence of the parameters within the design space, and thus more confidence in the robustness of the new method.

In this study we have employed a set of U-HPLC columns and have screened them for the analysis of various pharmaceutical samples on an integrated HPLC system designed for ultrafast automated method scouting. The system comprises gradient capabilities with multiple eluents for pressures up to 800 bar, an autosampler compatible with very short cycle times, and a powerful diode array detector with highest data collection capabilities. Two high-pressure column selection valves in the column compartment provide maximum scouting flexibility, and intelligent software makes parameter permutation easy. Finally, the software immediately identifies the optimum chromatograms from the large data set without the need of manual review of each chromatogram acquired.

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