

CHIMIA REPORT/COMPANY NEWS

Firmen stellen sich und ihre Produkte vor
Companies present themselves and their products

Interested in a contribution? Please contact
Swiss Chemical Society, info@scg.ch, +41 31 306 92 92

Shimadzu – LabSolutions MD Brings Structure to Method Development for Impurity Analysis

For pharmaceutical impurity analysis, the real challenge is not only finding a separation that works but finding one that can be trusted for routine use. Shimadzu's LabSolutions Method Development (MD) software is designed for exactly that purpose. Built around an Analytical Quality by Design (AQbD) approach, it supports the full method development workflow from screening to optimization and validation, while also reducing manual effort and helping analysts define a robust operating region, rather than a single fragile set of conditions.

A more efficient way to reach the right method

A good example of how LabSolutions MD functions in practice is the Shimadzu application note "Efficient Method Development on Pharmaceutical Impurities Based on Analytical Quality by Design". In this example, the separation of ketoprofen and its impurities is explored by varying mobile phase composition, column temperature and flow rate. Instead of relying on repeated trial runs and visual inspection alone, LabSolutions MD organizes the results into a design space, making the relationship between conditions and resolution much easier to interpret.

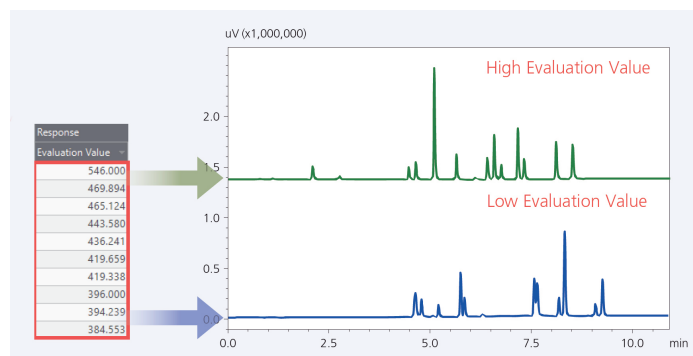
That is one of the main strengths of the platform. LabSolutions MD is a tool that improves the efficiency of the entire method development workflow through AQbD, with dedicated support for experimental design, space construction and robustness evaluation. The software can also rank chromatograms by separation performance, which saves time and helps you focus on the most promising conditions. In the application note, this led to a clear optimum: 40% acetonitrile, 35°C and 0.6 mL/min.

This is vital for laboratories under time pressure. The software does not simply collect data but helps turn data into decisions.

Automatic scheduling and screening functions that reduce the manual burden of method scouting are another highlight, which is especially useful when multiple mobile phases or columns must be evaluated. Moreover, it gives the analyst a clearer picture of where the method is forgiving and where it is not.

again in design space. The same approach is then repeated across different column lots, showing that the method remains stable even when the column source changes.

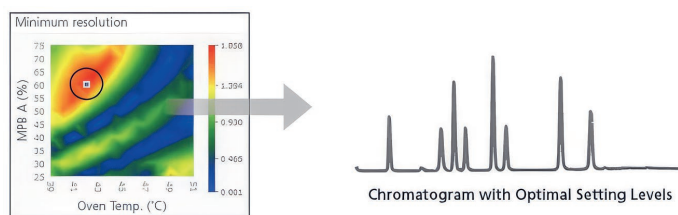
This is where the software moves beyond convenience: LabSolutions MD can support all three phases of AQbD-based analysis method development: initial screening, optimization and robustness evaluation. It can generate reports that summarize the experimental design, design space and chromatograms. Simultaneously it also manages the information in a database for data integrity. For regulated laboratories that combination is essential: it supports not only development efficiency, but also traceability and documentation.



The matrix view shown in the application note adds another practical advantage: By displaying many chromatograms at once, it makes comparison faster and more intuitive – especially when analysts need to judge subtle differences in separation quality across a large number of conditions. This visual clarity is part of what makes the software attractive for routine method development, where both speed and confidence matter.

LabSolutions MD is more than a screening tool. It is a method development environment built to help analysts move from scattered experiments to a defensible, robust method with less effort and greater transparency.

Link to Shimadzu Application Note:



Robustness that can be shown, not just assumed

The real value of LabSolutions MD becomes even clearer in the robustness phase. In the application note, the selected conditions are tested with small deliberate changes in acetonitrile content and temperature, and the resulting resolution is mapped

Contact

Shimadzu Schweiz GmbH
Hofackerstrasse 40B
CH-4132 Muttenz BL
+41 (0)61 717 93 33
www.shimadzu.ch

