Benefits of Automated HPLC Method Development and Transfer in Conjunction with Fast Chromatography

Abstract

The Waters Automated Method Development System (AMDS) provides an efficient automated solution to method development and transfer. We will discuss two significant applications of AMDS: (1) increasing productivity but at the same time reducing costs. However, batch-to-batch variation is greatly reduced without added cost (2) increasing the speed of development, allowing robustness before final validation. We have also found that AMDS is very helpful because of the trend of increased regulations. In the future, there have been an efficient approach to keep the development time and validation time under control.

AMDS Results

Peak 1: Desacetyl Diltiazem

Column: Acquity UPLC HSS T3, 150X2.1mm, 1.8µm
Mobile Phase A: 10mM Dihydrogen Phosphate Buffer pH 2.65
Mobile Phase B: Acetonitrile
Flow Rate: 0.4mL/min
Injection Volume: 10 µL
Detection: UV @ 290 nm
Gradient: Time (min) %A 0 100 10 100 20 100 30 100

Table: USP Diltiazem and related compound

<table>
<thead>
<tr>
<th>Compound</th>
<th>Formula</th>
<th>Retention Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diltiazem</td>
<td>C21H30O7S</td>
<td>2.5</td>
</tr>
<tr>
<td>Desacetyl Diltiazem</td>
<td>C21H28O6S</td>
<td>3.1</td>
</tr>
</tbody>
</table>

Taking that extra step yields profits

AMDS Set-up

Analyzed Drugs

Baseline simulation is very important in resolution

Using the Waters AMDS Automated Method Development System, peak resolution can be increased without any additional cost. Two different USP methods were set up to compare the benefits of AMDS. The original method was set up using manual peak picking and the Waters instrument was configured to run the method. The AMDS system was configured to run the method, the Robust pH Zone (RPZ) was calculated, the method was validated, the instrument was configured, and then the method was run on the Waters instrument.

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Discussion and Conclusions

In conclusion, automation by way of AMDS reduced manual effort by two-thirds compared to manual peak picking, and improved method performance by adding to the robustness of the method. In conclusion, AMDS is a powerful and efficient tool that can be used to improve the quality of HPLC methods and to reduce the time and cost of method development.

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