

Fusion QbD[®] – What You Can Accomplish in Just a Few Days!

Fusion QbD

Quality by Design Software System

WINDOWS[®]



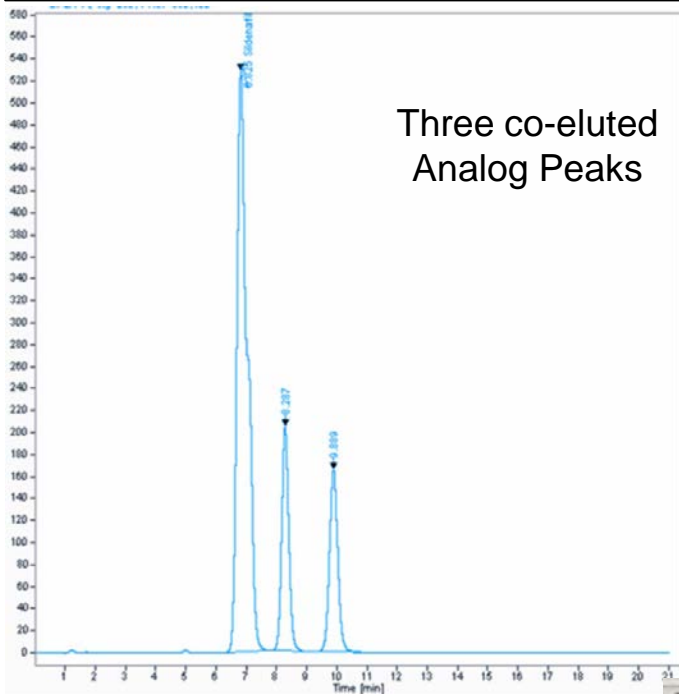
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What Was Accomplished in a Single Day!

More than 3 Months Development –
Trial and Error and Other Software:



FDA U.S. Food and Drug Administration
Protecting and Promoting Public Health www.fda.gov

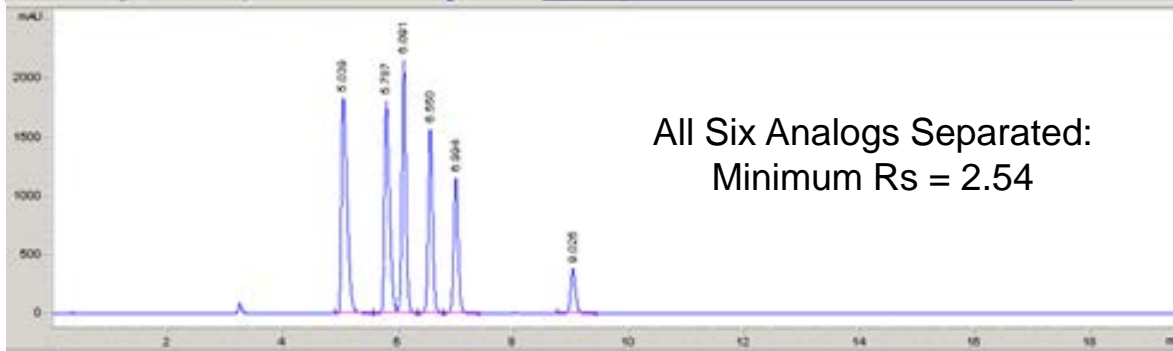
FDA-EMA Collaborative Research on Analytical Method QbD: Project Status

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FDA Division of Pharmaceutical Analysis

Disclaimer:
The findings and conclusions in this presentation have not been formally disseminated by the Food and Drug Administration and should not be construed to represent any Agency determination or policy.

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**One Overnight Screen
with Fusion QbD!**



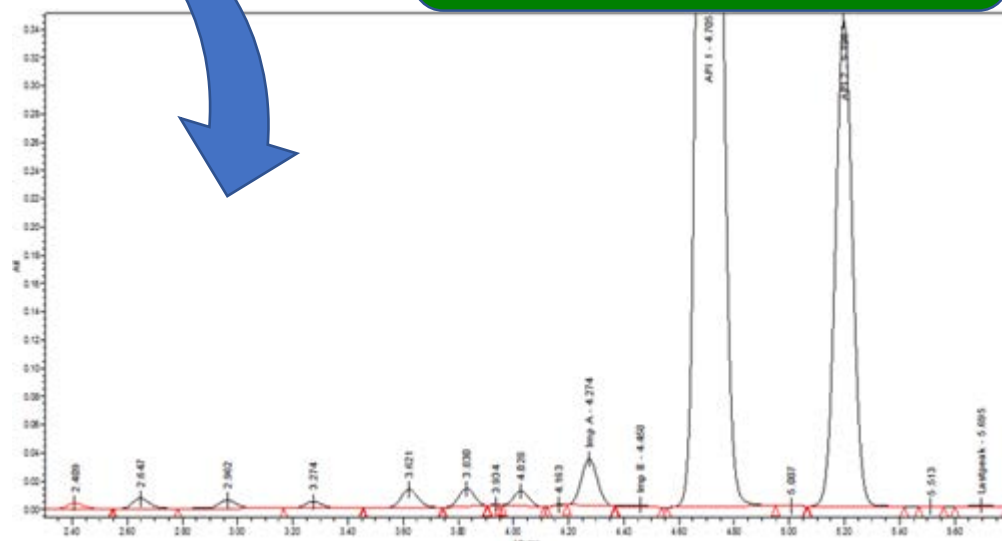
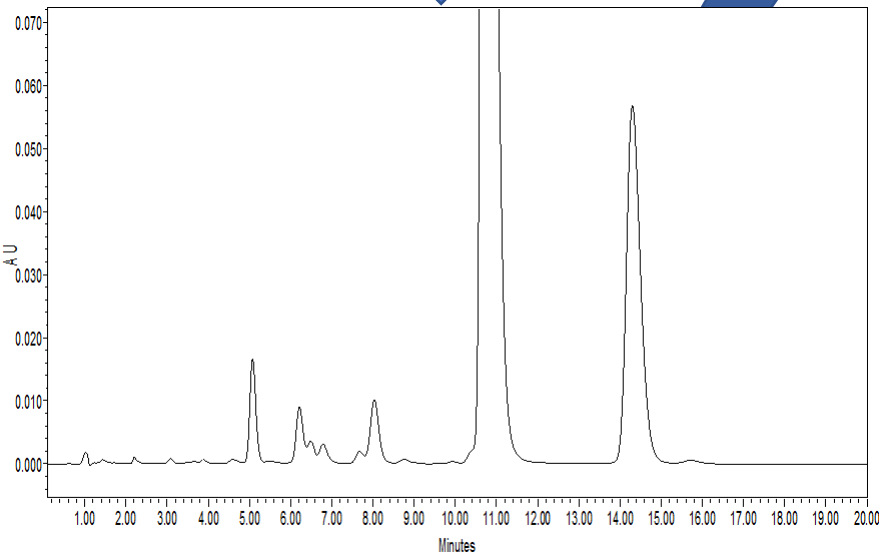
Final Robust Method in 3 Days!

More than 6 Months Development –
Trial and Error and Other Software:

- 1st – screened 10 columns
- 2nd – screened Isocratic & gradient conditions
- 3rd – screened gradient slopes
- 4th – screened mobile phase compositions

Major International
Pharma Company –
Natural Product

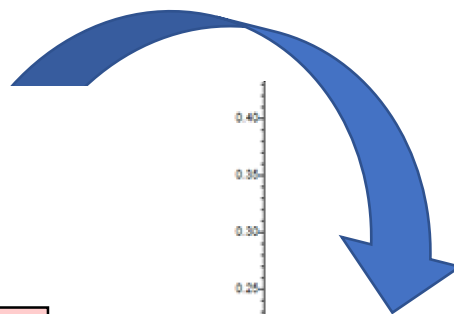
One Screening Run +
One Optimization Run
with Fusion QbD!



Final Robust Method in 1 Week!

More than 2 Months Development –

Trial-and-error work combined with off-line software for gradient slope optimization using %B versus Retention Time model.



Major International
Pharma Company –
New Drug Product

One Screening Run +
One Optimization Run
with Fusion QbD!

