Information sheet
Analytical services

Method optimization

Cambrex is **the** small molecule company that provides drug substance, drug product and analytical services across the entire drug lifecycle. Enjoy working with our experts to accelerate your small molecule therapeutics into the market.

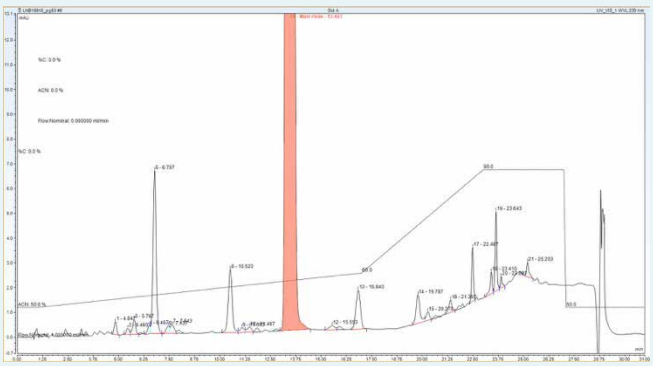
We offer a comprehensive method optimization service to take early stage development methods with poor stability indication, excessive run time lengths or legacy column chemistries and modify them, where desirable, to shorten run times, improve peak shape, confirm specificity for known related substances, peak resolution and to enable determination of LOD/LOQ.

Reducing run time

Original isocratic method of 70-minute length makes analysis run times impractical, especially for solid form projects with multiple (>20) samples provided per project milestone. A gradient was applied to allow earlier elution of late impurity peaks and reduce overall run time by over 50% to 31 minutes with all major impurity peaks accounted for and some previously unseparated impurity peaks identified. Further optimization of column length/flow rate/column temperature could result in even shorter overall run times whilst retaining peak selectivity.

Original 70 minute isocratic method

New 31 minute gradient method



Myra Rana
Analytical Scientist 2,
Analytical Development

Expertise

Method optimization
Method development
Method validation
Method transfer
Stability testing
Release testing

Techniques

- UHPLC UV & DAD
- LC/MS
- Gas chromatography (FID)
- Charged aerosol detection
- Particle size distribution
- Osmolality
- Intrinsic dissolution
- Apparatus II dissolution
- Coulometric Karl Fischer

For further information, please contact gary.oliff@cambrex.com at our Edinburgh facility