Information sheet
Analytical Services

Method optimization

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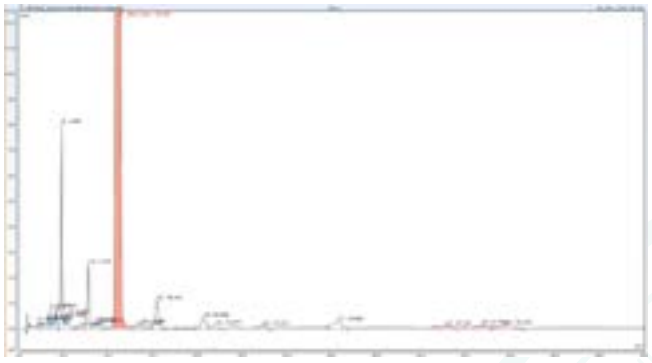
Analytical Development

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.

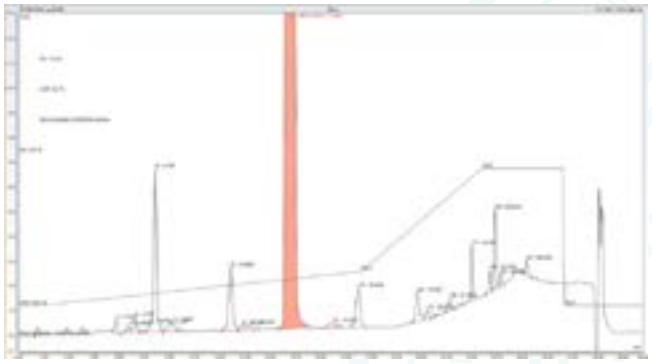
Reducing run time

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



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

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.

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