RESOLIAN
ANALYTICAL SCIENCES

Impurity Identification

Characterisation and monitoring of impurities using Ultra-Performance Liquid Chromatography and High Resolution Mass Spectrometry (UPLC-HRMS).

Knowledge of the impurities and degradation profile of drug substance and excipients is critical in understanding the stability, safety and efficacy of pharmaceuticals and biopharmaceuticals.

To identify, with a significant degree of certainty, low level impurities in the presence of high level components requires the combination of multiple analytical techniques and expert interpretative skills.

Our approach uses advanced chromatography and mass spectrometry platforms combined with innovative powerful software packages.

Together, the team of highly skilled scientists interrogates and interprets the data generated to elucidate the structure of individual or multiple unidentified components.

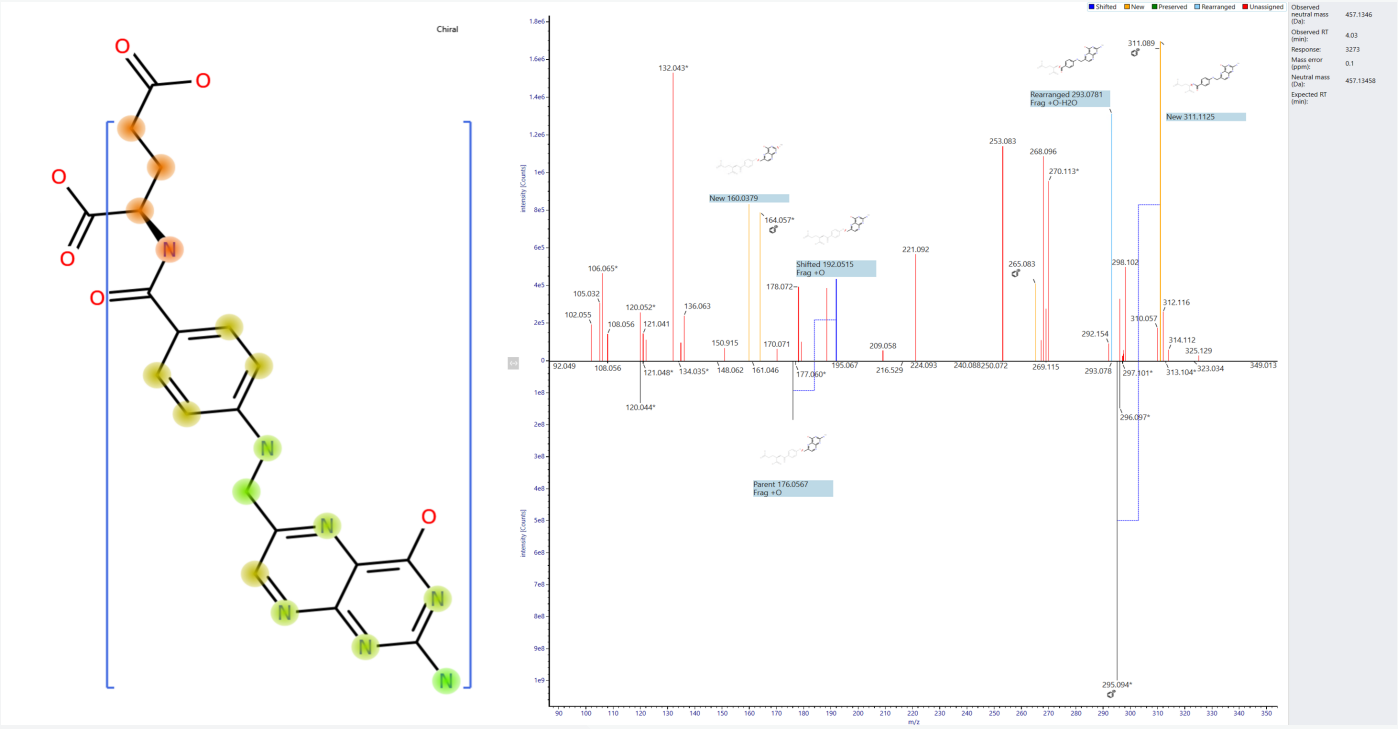

Figure 1: Molecular characterisation using advanced structural elucidation tools

Case example

Challenges

One example of quantifying impurities at very low levels involved an unknown degradation product of a human peptide hormone.

The sponsor had observed a new peak in the standard LC-UV chromatography during the stability assessment of the product.

Science

Our scientists established the sponsor's method on to an Acquity UPLC coupled to a Waters SynaptTM G2 mass spectrometer. The method was modified for maximum sensitivity and the data interpretation focussed on specific regions within the chromatographic run.

The data independent acquisition (DIA) enabled the simultaneous identification of components using the high resolution, accurate mass MS/MS fragmentation information (Figures 2 and 3).

Outcome

The data identified peptide sequences related to the human peptide hormone.

These peptide sequences identified a degradation pathway for this compound and highlighted a potential stability issue that previously had not been considered.

A value added service

Following the identification of an unknown species in your product, we can develop and validate appropriate assay and related impurity methods to support release testing and stability studies.

Our structural elucidation capabilities are also used to strengthen our Extractables and Leachables services in identifying unknown compounds from extraction studies.

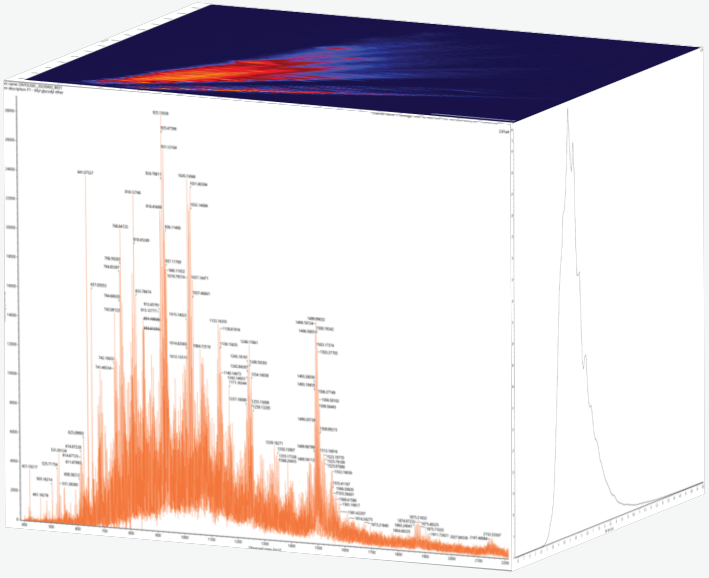

Figure 2: Data showing driftscope intensity, retention time, peak shape and mass spectrum

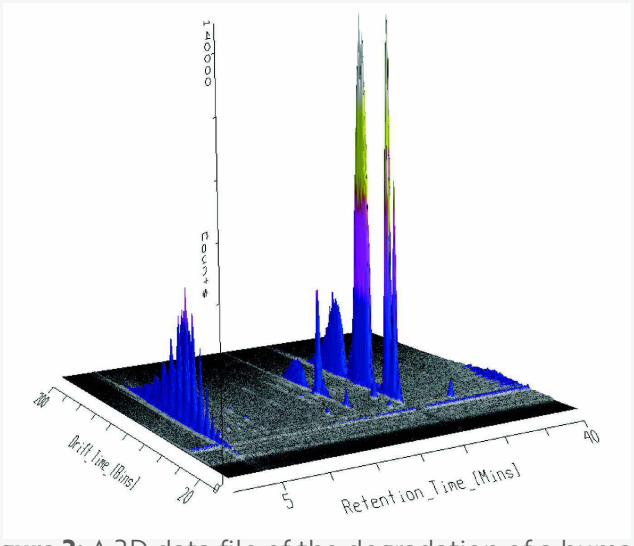

Figure 3: A 3D data file of the degradation of a human peptide hormone in solution

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