Development
(Small molecule)

Reliable and sensitive bioanalytical data

Perform studies with confidence using compliance-ready software

Support by a team of dependable experts

Introduction

Enhance your pharmaceutical development assays, while simplifying method development and reducing training needs. Our liquid chromatography-mass spectrometry (LC-MS) solutions are intuitive, robust and sensitive. All of our solutions are supported by compliance-ready software and trusted service professionals.

Accurately identify and monitor biomarkers, active pharmaceutical ingredients (APIs) and metabolites on a single software platform.

Featured applications and assays

Featuring: Introduction to quantitation by high-resolution mass spectrometry

- · ADME-Tox
- · Biomarker quantitation

Bioanalysis of:
- · Glucagon-like peptide (GLP-1) analogs
- · Nucleic acids and oligonucleotides
- · Peptides and cyclic peptides
- · Targeted protein degraders

Featured solutions

Routine bioanalysis

Triple quadrupoles have been the gold standard for bioanalysis for many years. The SCIEX Triple Quad 6500+ system offers trusted long-term performance. For ultimate sensitivity and extended robustness, the SCIEX 7500+ system is the solution of choice.

Complex samples

If you are challenged with coeluting compounds with similar masses, analytes with complex structure, a complex background with low abundant analytes or analytes with a high molecular weigh, a high-resolution mass spectrometer is a great choice. The SCIEX X500R QTOF system is the go-to system for most assays. Alternatively, the ZenoTOF 7600 system can be used for additional sensitivity and analytical horsepower.

Introduction to quantitation by high-resolution mass spectrometry

Easily quantify high-mass and complex analytes

Quantify co-eluting compounds with similar masses

Filter out complex background noise to see more in your sample

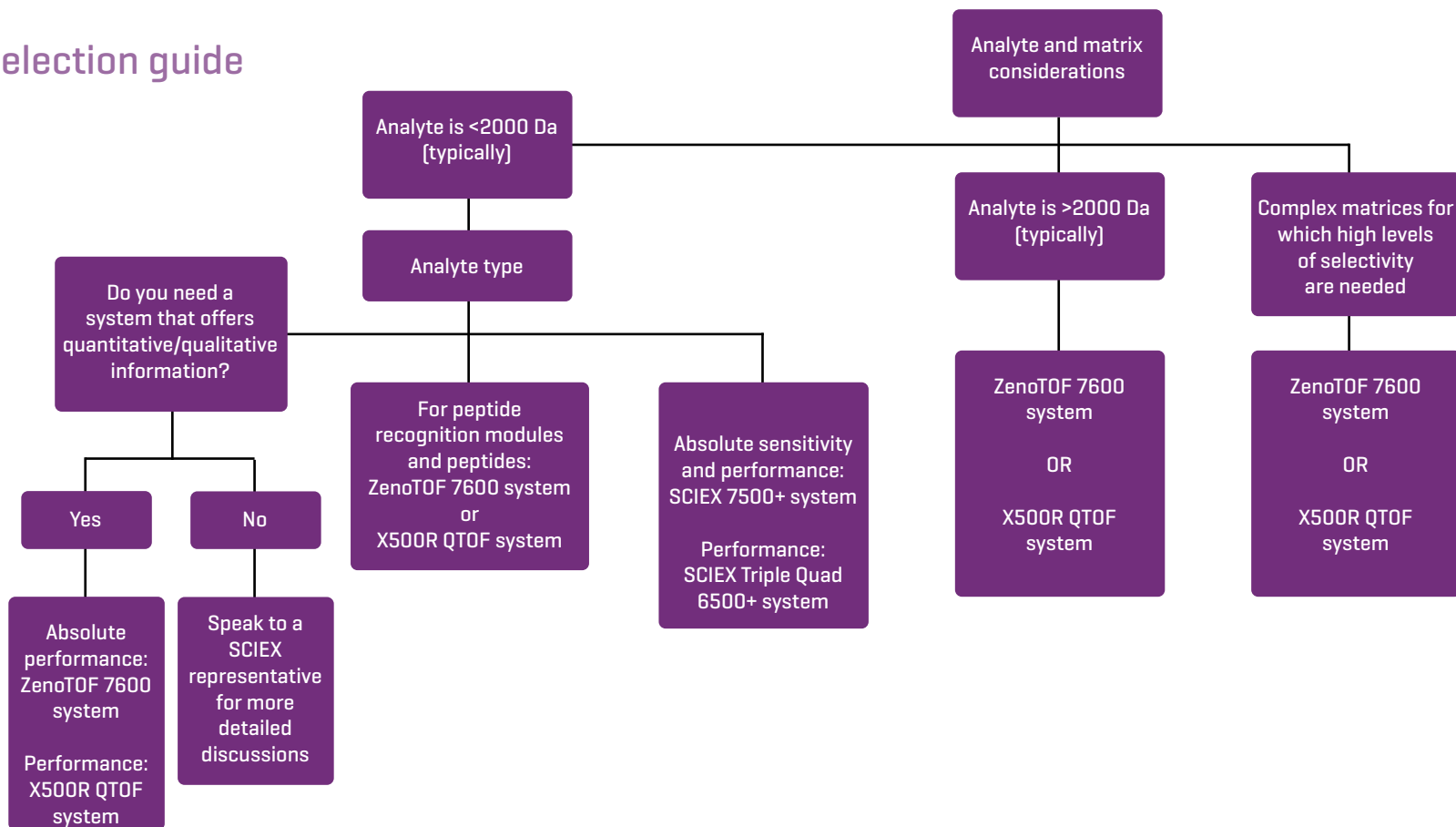# Benefits of high-resolution mass spectrometry for quantitation

SCIEX

Triple quadrupole mass spectrometers have been trusted for decades in pharmaceutical research and development for their quantitative performance.

In recent years, there has been a move to high-resolution mass spectrometry due to technology advancements, that have provided more sensitive and accurate quantitative performance. The appeal of high-resolution mass spectrometers is their ability to overcome the following challenges:

- Coeluting compounds with similar masses
- Separation of high background from low abundant analytes
- Quantitation of compounds with a high molecular weight

Quick system selection guide

Analyte and matrix considerations

Analyte is <2000 Da (typically)

Analyte is >2000 Da (typically)

Complex matrices for which high levels of selectivity are needed

Analyte type

Do you need a system that offers quantitative/qualitative information?

For peptide recognition modules and peptides: ZenoTOF 7600 system or X500R QTOF system

Absolute sensitivity and performance: SCIEX 7500+ system

Performance: SCIEX Triple Quad 6500+ system

ZenoTOF 7600 system

OR

X500R QTOF system

ZenoTOF 7600 system

OR

X500R QTOF system

Yes

No

Absolute performance: ZenoTOF 7600 system

Performance: X500R QTOF system

Speak to a SCIEX representative for more detailed discussions

Summary

We have worked with scientists across the drug development pipeline for decades, leading the way in quantitative mass spectrometry using quadrupoles. Our high-resolution systems are easy-to-operate, integrated analytical solutions that can provide rapid and reliable quantitative data with the added benefits of high resolution.

When you need support, SCIEX is here for you.

Fit-for-purpose solutions combining LC and high-resolution MS enable quantitation in complex matrices with excellent sensitivity and robustness, even at low levels.

ADME-Tox

Complex samples, and possibly low-level analytes, are common challenges that are faced every day by analysts working on ADME-Tox studies. Our fit-for-purpose LC-MS solutions enable pharmacokinetic parameters to be monitored in complex matrices with excellent sensitivity and robustness, even for low-dose, highly potent drugs. Simplify the monitoring of ADME-Tox parameters with compliance-ready SCIEX OS software.

- Perform ADME-Tox studies with confidence using compliant-ready software

- Acquire reliable and sensitive bioanalytical data using fit-for-purpose LC-MS solutions

Regulated and non-regulated ADME-Tox solutions for all stages of the pipeline

Highly sensitive LC-MS/MS method for the quantification of fluticasone propionate in human plasma using the SCIEX QTRAP 6500 system

Learn more about a highly sensitive and reproducible method for quantifying fluticasone propionate suitable for use in regulated bioanalytical labs using a simple solid-phase extraction technique.


BLANK

LLOQ (0.200 pg/ml)

ULOQ (120 pg/ml)
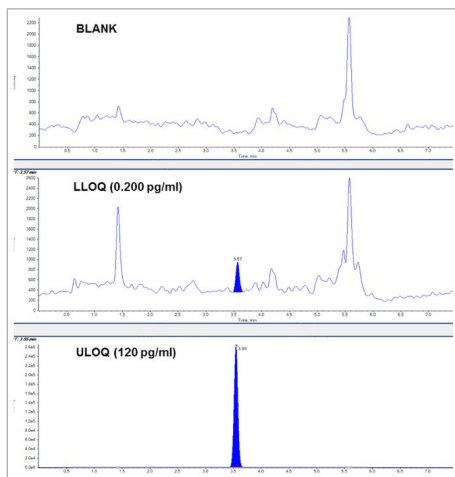
Sub-picogram detection of fluticasone propionate in plasma

Read more >

Low-level ADME-Tox analytes

A sensitive method for the quantification of formoterol in human plasma

Discover a quantitation method for low-dose, high-potency drug modalities combined with data acquisition and processing options that are simplified with SCIEX OS software, a 21 CFR Part 11-compliant platform.

Matrix blank | 0.05 pg/mL | 0.2 pg/mL
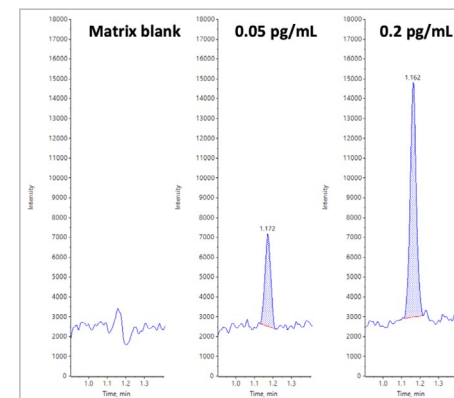
Representative extracted ion chromatograms (XICs) for formoterol in human plasma.

Read more >

Biomarker quantitation

Our systems provide in-depth coverage that enables you to characterize and confidently quantify biomarkers, including low abundant species. With different technology options for specific needs, we can help you get the answers you need.

- Achieve confident answers in hours instead of days

- Confidently identify and quantify small biomarkers with robust, sensitive analyses

- Improve workflows with support from our dependable team of experts

Targeted panel assays

High sensitivity quantification of acylcarnitines using the SCIEX 7500 system

Discover how you can quantify low-level acylcarnitine species with high throughput, robustness and reproducibility without requiring for derivatization.

Read more >
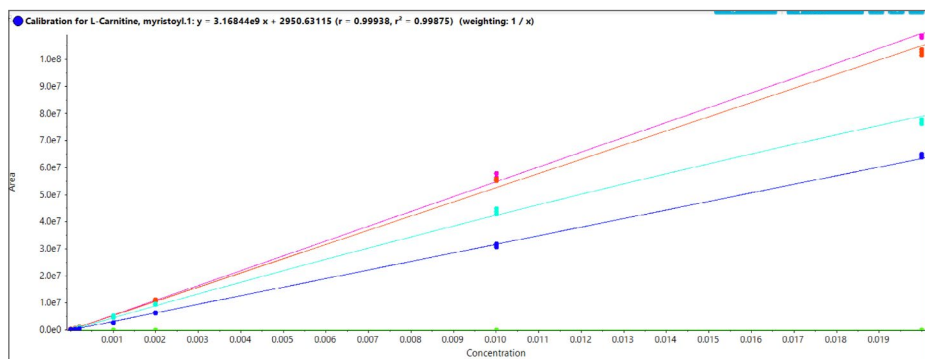
Linear dynamic range for several acylcarnitine compounds.

Identify and quantify unknowns

Identification and quantitation of lipid biomarkers using accurate mass spectrometry

Balance accurate quantitative performance with accuracy values between 80–120% at all concentration levels, with streamlined data management for acquisition and processing. Identification of lipid biomarkers becomes a simple task using the ChemSpider tool that is fully integrated into SCIEX OS software.

Read more >
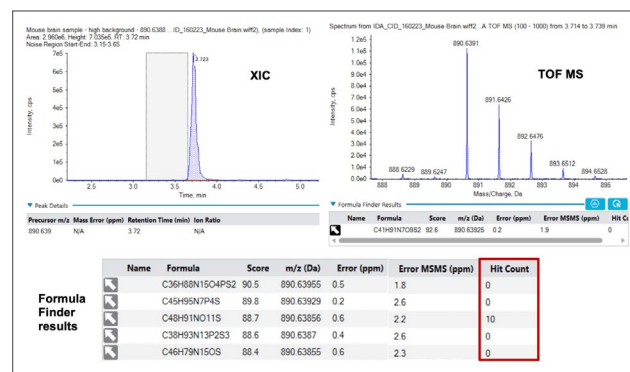
Using Zeno DDA to determine the interference observed at ~3.7 minutes

Glucagon-like peptides (GLP-1)

Highly sensitive analytical methods are required to understand the pharmacokinetic and pharmacodynamic profiles of GLP-1 analogs. Developing and running these methods is challenging due to their low oral bioavailability and their structure that yields poor ionization and fragmentation.

- Quantify GLP-1 analogs in complex biological matrices with outstanding reproducibility, precision, accuracy and linearity

- Employ a single platform for streamlined data acquisition, processing and management using SCIEX OS software

LC-MS/MS

Low-ng/mL quantitation of glucagon-like peptide-1 (GLP-1) analog in rat plasma

Discover options for a sensitive method to quantify a GLP-1 analog, semaglutide, in rat plasma with a lower limit of quantitation (LLOQ) of 0.2 ng/mL.

Read more >
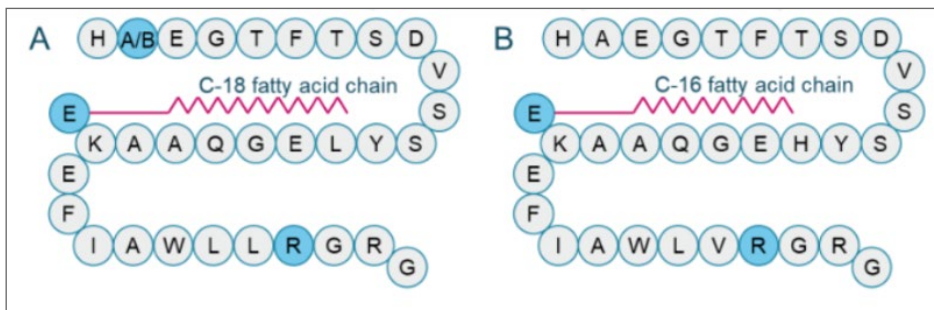
Structures of GLP-1 analogs. The left panel shows the structure of the target analyte, semaglutide (A) and the right panel shows the structure of the internal standard, liraglutide (B).

Enhanced robustness

Redefine bioanalysis with enhanced robustness on the SCIEX 7500+ system

This technical note demonstrates the measurement of alprazolam, sulfamethoxazole and diazepam in rat plasma matrix over 10,000 injections, with no divert valve. The SCIEX 7500+ system showed a >2x improvement in robustness for this analysis compared to the SCIEX 7500 system.

Read more >
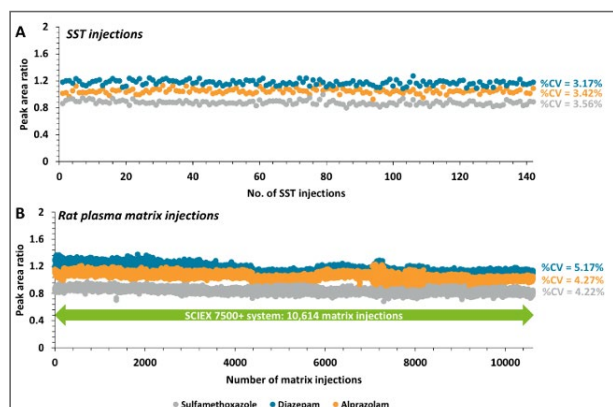
Peak area ratio (raw peak area normalized to IS) from analysis of alprazolam (orange), diazepam (blue) and sulfamethoxazole (grey) SST (A) and rat plasma matrix (B) injections on the SCIEX 7500+ system.

Peptides and cyclic peptides

Peptide and cyclic peptide analysis presents unique challenges compared to the analysis of a typical small molecule. Peptides are large, complex molecules that often contain multiple amino acids and post-translational modifications. This complexity results in a higher degree of structural variability, a wider dynamic range of concentrations and multiple charging when analyzed by mass spectrometry. Additionally, peptides are more prone to sample loss, degradation and modifications during sample preparation and analysis than typical small molecules.

- Our software allows you to automatically schedule multiple reaction monitoring (MRM) functions, retention times and MRM transitions for simple method optimization

- Easily develop and optimize quantitative workflows using the M5 MicroLC system with seamless integration into SCIEX OS software to enhance the sensitivity of a method

Peptide: Targeted panel

Reproducible targeted peptide profiling using highly multiplexed MRM assays

Read about a simplified method development approach for large-scale targeted peptide analysis. By using our Scheduled MRM function, retention times and MRM transitions are automatically optimized to create an acquisition method based on a few key parameters provided by the user.

Read more >
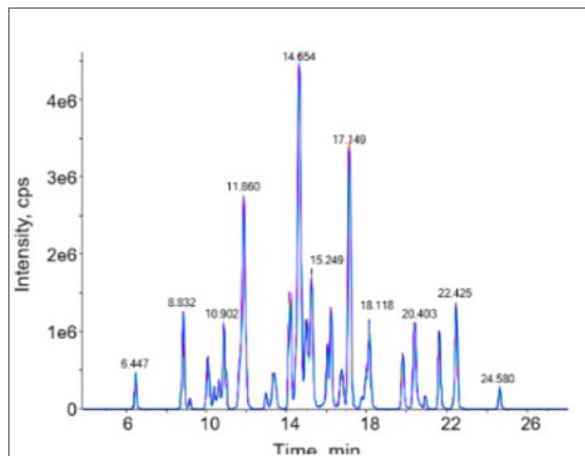
Chromatographic reproducibility for 30 min gradient runs.

Low-level cyclic peptides

Low-pg/mL quantification of cyclic peptides in rat plasma using microflow LC

Read about how to achieve low-level quantitation for human ANP at an LLOQ of 0.01 ng/mL in rat plasma with %CV values <12.3% at all concentration levels across inear dynamic range spanning 4.3 orders of magnitude.

Read more >
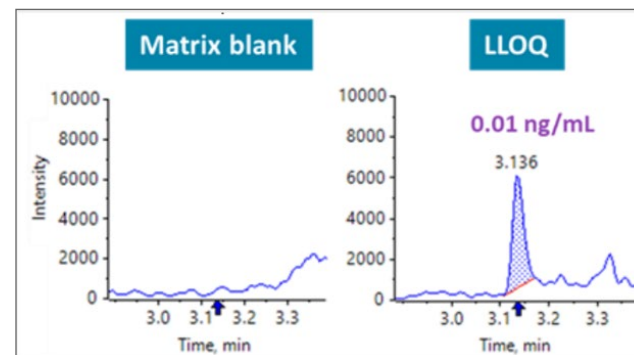
Extracted ion chromatograms (XICs) of a matrix blank and LLOQ sample of human ANP.

Nucleic acids and oligonucleotides

Synthetic nucleotide analysis is a complex pursuit because these drugs combine the learnings from nature's mechanisms with sophisticated technology. The diverse landscape of structural adaptations for bases and backbones has the potential to treat diseases with unprecedented specificity but also increases the challenges for analyzing synthetic oligonucleotides.

- Complete sequence confirmation, impurity identification, sizing and purity analysis with cutting-edge analytical solutions

- High-quality results for therapeutic oligonucleotides (antisense oligonucleotides, siRNA, aptamers) help you advance medicine

Quantitation of nucleic acids

Quantitative LC-MS solution for targeted analysis of cell culture media

Discover options for the measurement of polar and nonpolar analytes, in addition to positive and negative polarity components within a single method.

Read more >
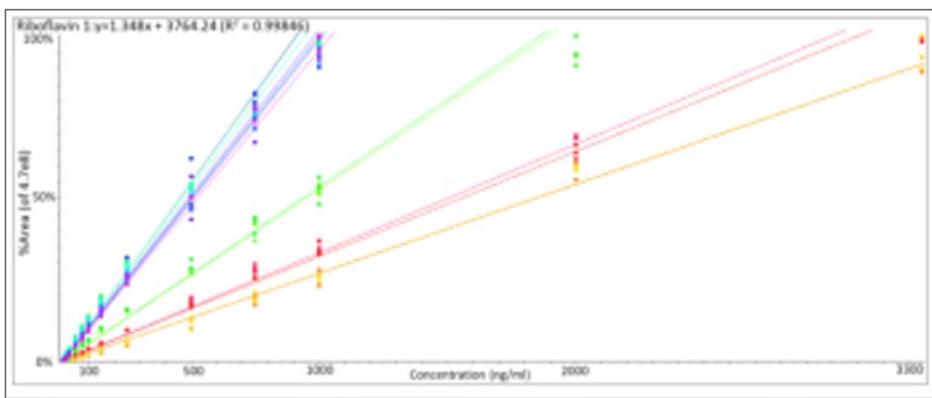
Linear calibration curves of representative cell culture component per group measured in positive and negative modes.

Identify and quantify unknowns

Characterization and relative quantification of oligonucleotide impurities

See how robust data quality and high mass accuracies provide confident assignment of oligonucleotide FLP and impurities using the Molecule Profiler software. The use of this software allowed straightforward relative quantitation based on the TOF MS peak.

Read more >
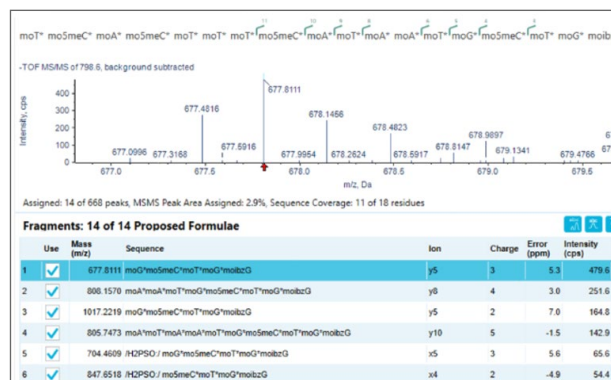
Confirmation of the sequence of the potential ASO-18PS2MOE impurity with 1 isobutyryl protecting group on G.

Targeted protein degraders

Lead the development of novel targeted protein degradation (TPD) therapeutics, such as proteolysis-targeting chimeras (PROTACs). Bring novel drugs based on this new class of compounds to market with analytical systems that enable precise and accurate identification and quantitation of low-level targeted protein degraders, even in complex matrices. Get to the important information quickly with fast, intuitive and integrated data acquisition and processing software.

● Achieve sensitive quantitation of targeted protein degraders with excellent accuracy and precision

● Comfortably work with complex matrices

Quantitation

Low-pg/mL quantification of TL 13-112, a protein-targeting chimera (PROTAC) in rat plasma

See how it is possible to achieve low-pg/mL level LLOQs for the quantitation of PROTACs in rat plasma with robust analytical performance. These results were achieved in combination with streamlined, compliance-ready data management.

Read more >
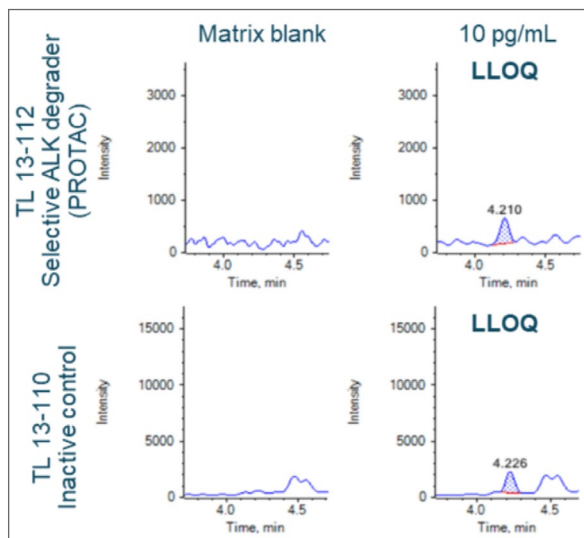
Representative XICs of the selective ALK degrader (PROTAC) and its inactive control in matrix and at the LLOQ level.

A sensitive method for the quantification of the protein targeting chimera (PROTAC), TL 13-12, in rat plasma using accurate mass spectrometry

Achieve an LLOQ of 0.3 ng/mL for the quantitation of TL 13-12 and TL 13-22 in rat plasma using MS/MS data acquisition. This approach allows you to minimize sample volume and sample preparation time.

Read more >
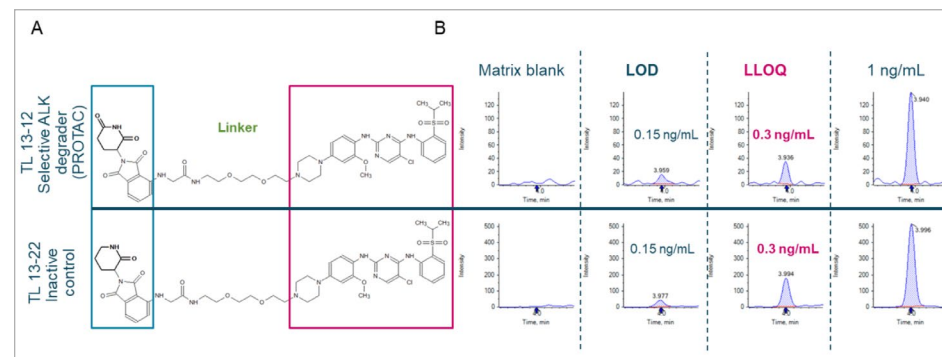
Sub-ng/mL level quantitation was achieved for the PROTAC and its inactive control.

Conclusion

Simplify your pharmaceutical development assays to save time and reduce the training needs of the scientists working in your team. Our LC-MS solutions, including our software and trusted services and support, are intuitive, robust and sensitive.

Additional links for development assays

Selecting the right system for bioanalytical quantitation
Investing in a new LC-MS system is not an easy decision, especially if you have a range of analytical requirements in your laboratory. This blog is intended to help you choose the right system for your pharmaceutical drug development needs.

Read blog >

Easing the demands of a compliant pharmaceutical laboratory
At SCIEX, we are proud to provide analytical systems to the pharmaceutical industry. We work hard to understand the demands of analytical work and the processes required to develop and manufacture drugs. This blog provides an overview of some of the ways we are here to help.

Read blog >

Sensitive LC-MS/MS approach for the quantification of proteolysis-targeting chimeras in a biological matrix
In this webinar, we explore a sensitive LC-MS/MS workflow for quantifying PROTACs in a biological matrix using the SCIEX 7500 system.

Watch webinar >

Driving more sensitive bioanalysis using accurate mass spectrometry
Quadrupole-based LC-MS has been routinely adopted for the quantitation of therapeutics in bioanalytical laboratories. Advances in accurate mass spectrometry have enabled it to become a complementary option for quantitative bioanalysis. These advances include greater selectivity, improved mass resolution and the flexibility of time-of-flight (TOF) MS/MS for data analysis.

Watch webinar >

Enhancing quantitative sensitivity in cerebrospinal fluid
This webinar discusses the sensitive quantitation of LRRK2 at 10 pg/mL in human cerebrospinal fluid. Dylan Bennett, a scientist at Neuron23, shares the details of this LC-MS/MS methodology for the sensitive analysis of this promising target.

Watch webinar >

Identification and quantitation of lipid biomarkers using high-resolution MS
In this webinar, our speaker discusses the role of glucosyl and galactosyl ceramides as biomarkers and how their misregulation can be an identifier for various disease states including, but not limited to, Parkinson's, Krabbe and Gaucher diseases.

Watch webinar >

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- SCIEX Now Learning Hub success programs provide LC-MS and CE training customized to meet your exact needs

- With a selection of training methods and certifications available, you can build a mass spectrometry learning program that is most suited to your lab and users

- By starting with a clear understanding of your desired learning outcomes, we help you improve lab productivity and consistency by designing and delivering a program that is focused on knowledge advancement and retention

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