ThermoFisher SCIENTIFIC

Pharma and biopharma

Innovation meets reliability

Discover new levels of precision in your routine analysis

Your partner for every step in your therapeutics journey

When you're advancing life-changing therapeutics to market, your analytical science deserves more than standard solutions. That's why Thermo Fisher Scientific comes alongside you with comprehensive solutions—helping replace stress with confidence, risk with reliability, and complexity with consistency. Explore an award-winning fleet of chromatography and mass spectrometry (MS) systems, plus compliance-ready software, responsive service, and support. Get what you need to power your progress—and redefine results. Where innovation meets reliability, Thermo Fisher Scientific is by your side.

Early discovery and research

High-throughput capabilities and versatile, advanced tools.

Product characterization

Advanced tools to answer in-depth molecular questions.

Process and analytical development

Robust and reproducible analyses to monitor molecular attribute changes with speed and confidence.

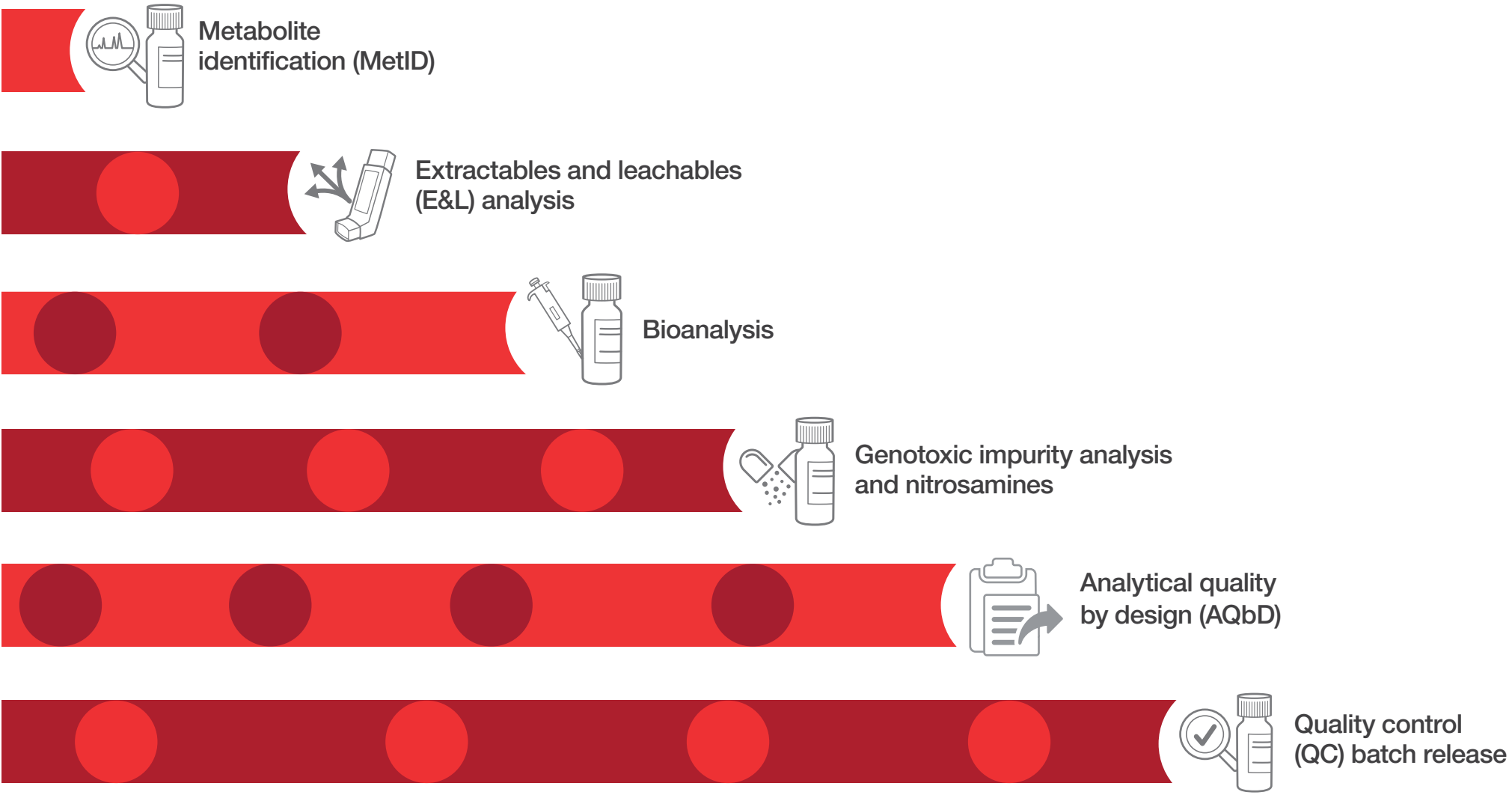
Quality control and manufacturing

Reproducible, robust, cGMP compliance-ready methods.

From discovery to commercialization, Thermo Fisher Scientific provides expertise and a superior portfolio of scalable tools, services, and support, designed to deliver high-quality results and accelerate your productivity and innovation.

Analytical workflows for your critical analyses

Designed for efficiency and reliability, our solutions empower you to generate high-quality analytical results with speed and accuracy, enabling deeper insights and streamlined decision-making across diverse pharmaceutical and biopharmaceutical applications. Our robust portfolio of pharma workflow solutions are tailored to the rigorous demands of pharmaceutical characterization, quality control, and regulatory compliance.

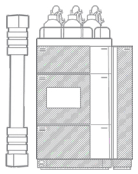


Metabolite identification (MetID)

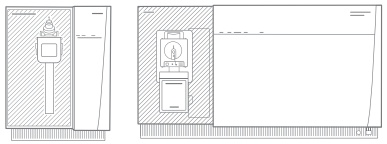
Increased confidence in drug MetID through intelligent data acquisition

MetID is a crucial and integral part of drug discovery and development. Confident metabolite annotation generally requires fragmentation data to allow structure elucidation. Rapid metabolism reduces the duration and potential efficacy of pharmaceuticals. In early drug discovery stages metabolic profiling is employed to identify metabolic soft spots to inform optimization of lead compounds. Additionally, metabolic profiling plays a critical role in evaluating the safety of the molecule.

Metabolite identification



Thermo Scientific™ Hypersil GOLD™ VANQUISH™ C18 UHPLC Columns and Thermo Scientific™ Accucore™ Vanquish™ C18+ UHPLC Columns



Thermo Scientific™ Orbitrap™ Exploris 240 MS and Thermo Scientific™ Orbitrap™ Tribrid™ MS

Thermo Scientific™ Xcalibur™ software for data acquisition with Acquire X Thermo Scientific™ Compound Discoverer™ software

Thermo Scientific™ Vanquish™ UHPLC Systems and Thermo Scientific™ Orbitrap™ Tribrid™ MS offers the optional capability to fragment precursors with ultraviolet photodissociation (UVPD) generating unique fragments complementary to collision-induced dissociation (CID) and higher-energy collisional dissociation (HCD) to obtain detailed structural information. Thermo Scientific™ AcquireX™ software background exclusion workflow excludes matrix ions from triggering Data Dependent Acquisition (DDA). This allows users to lower the MS/MS triggering intensity threshold to trigger more low-level metabolites and increase identification efficiency. Screen, identify and quantify compounds in complex samples rapidly and with confidence using the Thermo Scientific™ Orbitrap™ Exploris 240 Mass Spectrometer.

Added value

- Comprehensive metabolite profiling through high-quality high-resolution accurate mass (HRAM), MS, and MS/MS data—acquired with high resolution, high scan speeds, fast polarity switching, and internal calibration
- AcquireX software background exclusion workflow significantly improves the fragmentation data coverage for relevant metabolites, reducing the need for re-analysis of samples after initial data processing
- Real-time library search to guide data acquisition based on structural similarity to provide more meaningful deep fragmentation data
- Orthogonal fragmentation techniques such as UVPD can provide complementary information to HCD and CID to aid in elucidating the site of metabolism, especially for labile metabolites

Increased confidence in drug metabolite identification through intelligent data acquisition strategies and multiple fragmentation techniques on the Orbitrap Tribrid MS platform

Confident transformation site localization of PROTAC drug metabolites facilitated by multi-stage fragmentation LC-MS

Extractables and leachables (E&L) analysis

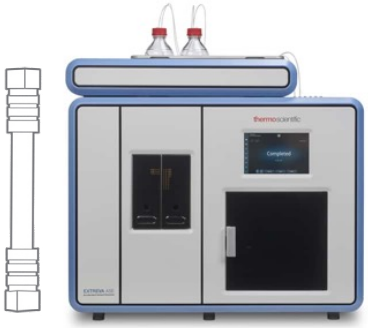
Advanced techniques for extractables and leachables testing

E&L analysis encompasses characterization and quantification of unknown compounds in pharmaceuticals or medical devices. This requires multiple analytical technologies to analyze a variety of compounds encompassing volatile, semi-volatile, and non-volatile impurities.

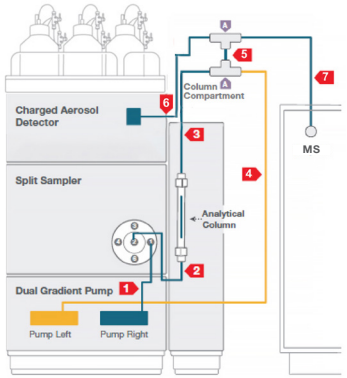
Extractables and leachables

Challenges with E&L analysis

- Confident identification of unknowns
- High analytical uncertainty factors affecting analytical evaluation thresholds (AETs) when using liquid chromatography-mass spectrometry (LC-MS)



Thermo Scientific™ Hypersil GOLD™ VANQUISH™ C18 UHPLC Columns and Thermo Scientific™ Extreva™ ASE™ Accelerated Solvent Extractor



Thermo Scientific™ Vanquish™ LC System with Charged Aerosol Detector (CAD) or Diode Array Detection (DAD) UHPLC with Thermo Scientific™ Orbitrap Exploris™ 120 MS

Thermo Scientific™ Xcalibur™ software or Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS)
Thermo Scientific™ Compound Discoverer™ software
Thermo Scientific™ mzCloud™ database for E&L, molecule high-resolution accurate mass (HRAM), and MS library searching

Added value

- Simultaneous acquisition of orthogonal UV, CAD, and MS data
- Thermo Scientific™ Vanquish™ Inverse Gradient LC Systems allows for higher confidence in standard-free quantitation by providing uniform signal response for CAD
- Thermo Scientific™ Hypersil GOLD™ VANQUISH™ C18 UHPLC Columns for reproducible separation
- Mass proportional response of charged aerosol detector
- The workflow provides increased confidence and completeness of E&L analysis by extracting more data from a single injection

A reliable UHPLC/UV/CAD/MS multidetector method for routine quantification and library matching of extractables and leachables in pharmaceutical-grade plastics

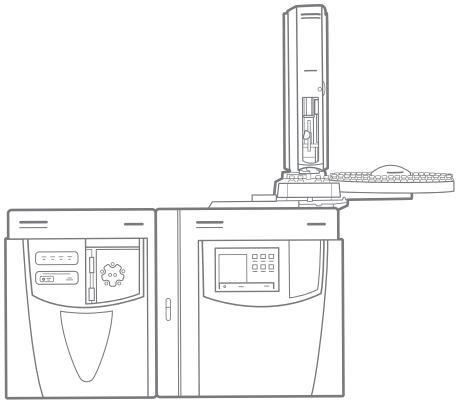
Extractables and leachables (E&L) analysis

Advanced techniques for extractables and leachables testing

E&L analysis encompasses characterization and quantification of unknown compounds in pharmaceuticals or medical devices. This requires multiple analytical technologies to analyze a variety of compounds encompassing volatile, semi-volatile, and non-volatile impurities.

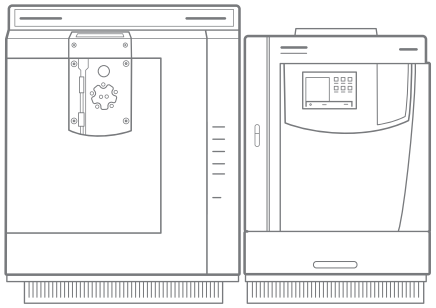
Extractables and leachables

Solvents and volatiles identification and analysis in pharmaceuticals and biopharmaceuticals is essential, because they can be toxic to the patient or affect drug efficacy. We have proven, simple, compliant workflows for organic volatile impurities that follow regulatory guidelines, such as pharmacopeial chapter USP <467> Residual Solvents, and ICH Q3C Guideline for Residual Solvents.



Thermo Scientific™ ISQ 7610 Single Quadrupole GC-MS System

Semi-volatile organic pharmaceutical impurities are a complex range of chemicals that often require high selectivity and sensitivity analysis for identification and quantification. Obtain unambiguous impurity identification and quantification with exceptional performance using Thermo Scientific™ Orbitrap™-based mass spectrometry with software that utilizes advanced filtering algorithms and automates library searching.



Thermo Scientific™ Orbitrap™ Exploris™ GC Mass Spectrometer

Added value

- The ISQ 7610 Single Quadrupole GC-MS System combines robustness with the ability to change the GC column and clean the ion source without interrupting your analytical workflows
- Extended linear range enables method consolidation so you can analyze more compounds at varying concentrations in a single run
- Offers the power and flexibility of full-scan high-resolution accurate mass data to quantitative, screening and discovery workflows
- Offers the option to configure the system with either 30,000 or 60,000 mass resolving power and the ability to add MS/MS capability today or in the future

Bioanalysis—small molecule

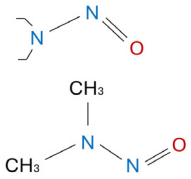
Fast, robust, and sensitive quantitation

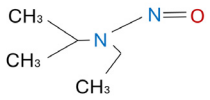
Bioanalysis requires the ultimate performance—speed, resolving power, and robustness—all in the presence of a complex biological matrix. With hundreds of samples processed on each system per day, fast separation is employed and must remain stable. This in turn means more strain on the resolving power and scan speed of the detector. Good sample preparation is a must, and the ability to perform clean, reproducible solid phase extraction off-or on-line as needed adds another layer of robustness.

Bioanalysis—small molecule

Selective sample preparation

Thermo Scientific™ SOLA™ Solid Phase Extraction (SPE) plates provide selective isolation of target compounds with additional concentration for sensitivity. Frit-less technology provides high repeatability of extraction characteristics.

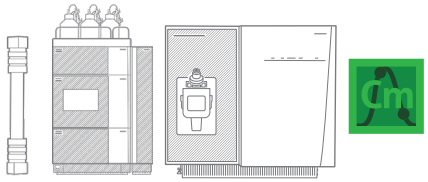




Ultimate sensitivity

Vanquish Flex or Horizon UHPLC systems provide robustness with speed and sensitivity.

Hypersil GOLD™ VANQUISH™ C18 UHPLC Columns



Highly robust platforms design with high throughput and sensitivity in mind. Thermo Scientific™ TSQ Altis™ Plus MS enables robust, fast, and sensitive quantitation experiments. Chromeleon CDS offers compliance-ready software with a direct link to laboratory information management systems (LIMS).

Added value

- Selective sample preparation enhances robustness and accelerates analysis
- Thermo Scientific™ Hypersil GOLD™ VANQUISH™ C18 UHPLC Columns for improved reproducibility and fast separation
- TSQ Altis plus provides exceptional selectivity with high-resolution (0.2 Da FWHM) selected-reaction monitoring (H-SRM) performance to improve signal-to-noise ratios for targeted compounds

SOLA Solid-Phase Extraction (SPE) cartridges and plates

Chromeleon CDS workflow for bioanalysis

Bioanalysis—large molecule

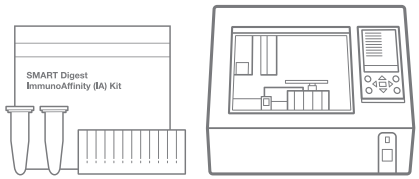
Fast, robust, and sensitive quantitation

The rise in large molecule biotherapeutics, which are more complex and challenging to analyze, has increased the demand for protien based, and RNA based molecule bioanalysis using mass spectrometry. Triple quadrupole and high-resolution accurate mass orbitrap technology provides ultimate selectivity for the analysis of biotheraputic based products. A unique combination of innovative technologies provides a workflow with superior quantitative accuracy and sensitivity. Good sample preparation is a must, and the ability to automate affinity capture steps and digestion as needed adds another layer of robustness.

Molecule bioanalysis—large molecule

Streamlined sample preparation

Thermo Scientific™ Kingfisher™ purification systems and Thermo Scientific™ SMART Digest™ kit provides fast and simple protein capture and/or digestion with high reproducibility and sensitivity, in a format that's compatible with automation.

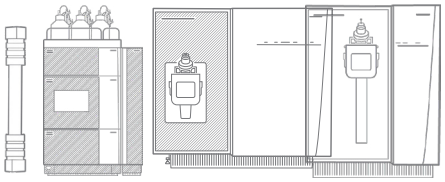


Biotherapeutic proteins

Surrogate peptide analysis

Ultimate sensitivity

Vanquish Flex or Horizon UHPLC systems provide robustness with speed and sensitivity. Highly robust platforms design with high throughput and sensitivity in mind.



- TSQ Altis Plus MS enables robust, fast and sensitive quantitation experiments
- Orbitrap Exploris 120 MS provides accessible high resolution analysis for when ultimate selectivity is required
- Chromeleon CDS offers compliance-ready software with a direct link to LIMS

Added value

- Automated sample preparation increases robustness and accelerates the analysis
- Thermo Scientific™ DNAPac™, Thermo Scientific™ MAbPac™, and Thermo Scientific™ ProPac™ Columns ensures fast resolution of large molecules
- Orbitrap Exploris 120 MS combines operational simplicity with ultimate resolution capability
- TSQ Altis plus provides exceptional selectivity with high-resolution (0.2 Da FWHM) selected-reaction monitoring (H-SRM) performance to improve signal-to-noise ratios for targeted compounds

Sensitive LC-MS/MS quantitation of antisense oligonucleotides in plasma using the TSQ Altis Plus mass spectrometer

A fast and simple immuno-mass spectrometry method for preclinical bioanalysis for IgG1 mAb

Chromeleon CDS workflow for bioanalysis

Sensitive quantitation of antisense oligonucleotides in plasma using high-resolution, accurate-mass (HRAM)

Genotoxic impurity analysis and nitrosamines

Ingredient monitoring

To minimize the *in-situ* formation of nitrosamines in pharmaceuticals, either during manufacturing or storage, it is important to accurately assess the precursors such as nitrite and secondary amines as part of risk assessment and QC.

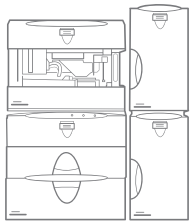
Ingredient monitoring

Challenges

- Nitrite is present in a variety of sources such as excipients, raw materials, and pharmaceutical packaging
- The highest risk of nitrosamine formation is during wet granulation
- Secondary amines and secondary amine containing APIs (in the presence of acidic conditions) can undergo nitrosation, resulting in mutagenic alkyl nitrosamine drug substance-related impurities (NDSRIs)

Thermo Scientific™ Dionex™ ICS-6000 HPIC™ System

- Reagent-free eluent generation
- Fast sensitive separations with up to 5000 psi
- Dual analysis channels for increased throughput



Chromeleon CDS

- Intuitive instrument control for easy execution of analysis
- Easy-to-use software for data processing

Added value

- Protect brand reputation and reduce the risk of formation of nitrosamines and NDSRIs leading to batch recalls
- Keep more active pharmaceutical ingredients (APIs) on the market for revenue maximization
- Minimize risk to nitrosamines reaching the final pharmactical product keeping patients safe and healthy

Determination of nitrite in pharmaceuticals

Designing ion chromatography methods for determining amines in pharmaceuticals

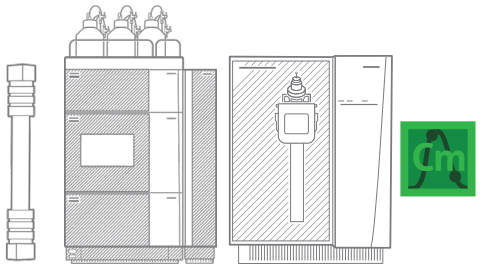
Genotoxic impurity analysis and nitrosamines

Nitrosamine analysis

To minimize the *in-situ* formation of nitrosamines in pharmaceuticals, either under manufacturing or storage, it is important to accurately assess the nitrosamines and nitrosamine drug substance related impurities (NDSRIs) in the API and final product during AD and QC.

Nitrosamine analysis—analytical development (AD)

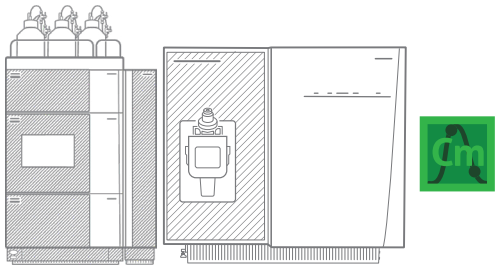
Thermo Scientific™ Acclaim™ 120 C18 Column



Orbitrap Exploris 120 MS

- Intuitive instrument control for easy execution of analysis
- Easy-to-use software for data processing
- Ultimate confidence for impurity analysis

Nitrosamine analysis—quality control (QC)



TSQ Quantis Plus Triple Quadrupole MS

- Experience reliability and report results with confidence
- Robust high-throughput analysis
- High sensitivity and selectivity in SRM mode

Added value

- Reduce the risk of formation of nitrosamines and NDSRIs leading to batch recalls
- Keep more APIs on the market
- Minimize risk to nitrosamines reaching the final pharmactical product keeping patients safe and healthy

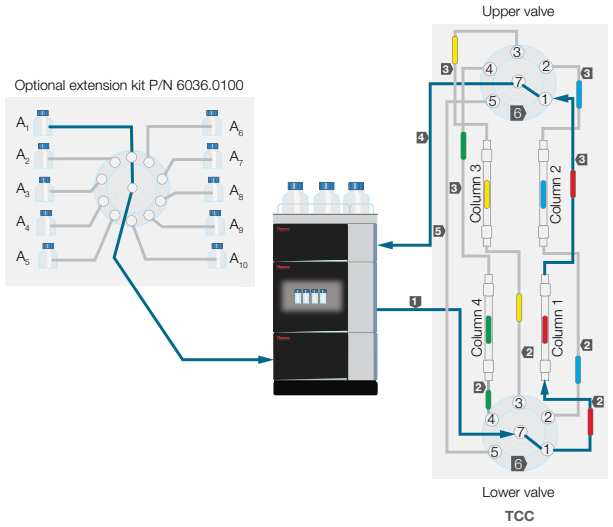
Genotoxic impurity analysis by LC-MS/MS

Sensitive and robust determination of genotoxic AZBT impurity in six sartan drug products

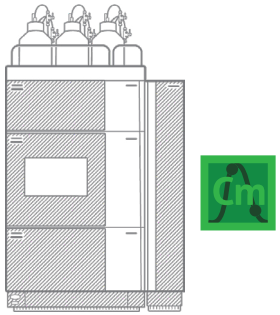
Analytical quality by design (AQbD)

Enhanced approach to method development

The goal of development is to obtain an analytical procedure fit for its intended purpose: to measure an attribute or attributes of the analyzed material with the needed specificity/selectivity, accuracy, and/or precision over the reportable range. Applying an enhanced approach to method development can lead to more robust analytical procedures, better understanding of the impact of analytical procedure parameters, and more flexibility for lifecycle management—such as wider operating ranges, a more appropriate set of established conditions (ECs), and associated reporting categories for changes.



Analytical quality by design



Develop and test new methods quickly and easily

Vanquish Core HPLC and Vanquish Flex UHPLC systems are ideal for robust separation. The automated method scouting kits allow fast method development. Compatible with industry standard AQbD software for data interpretation and validation.

Added value

- Automated method scouting kits make it simple to test multiple LC parameters in a single batch to find optimal conditions
- Compatible with third–party AQbD software to test robustness and validate the conditions
- Extremely robust (U)HPLC separation on the Vanquish systems increase confidence and reduce uncertainty

Development of a robust LC method for metolazone and related impurities using analytical quality by design best practices

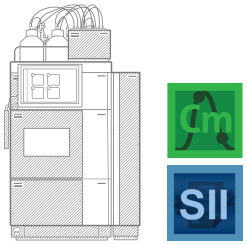
Automated UHPLC method development for mebendazole and related impurities, from method scouting to robustness testing

Quality control (QC) batch release

Reliable results and confident method transfer

High throughput and confidence in the results is key to having confidence in product release. Methods are locked down through validation and need to be transferred across platforms and even laboratories. Any deviation or performance issues need to be investigated and so robust platforms, and the ability to transfer methods within strict performance criteria, are essential.

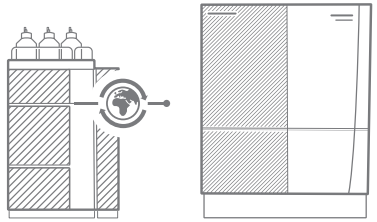
Quality control (QC) batch release



Thermo Scientific™ Vanquish™ Core HPLC systems

To improve your lab's productivity while maintaining existing workflow, you need a system that has the flexibility to perfectly replicate your current methods. The Vanquish Core HPLC system is designed to mimic other HPLC systems to simplify transfer of methods while boosting productivity and ease of operation.

- Adjustable gradient delay volume to replicate solvent conditions throughout your run
- Injection programs to adapt for high organic solvents
- Still-air and forced-air thermostatting options to mimic your existing instrument
- Either run in Chromeleon CDS or in third party software via the Standard Instrument Integration (SII) plugin



Flexibility of detection

Hyphenate additional methods of detection for those compounds not amenable to UV detection. CAD and single quadrupole mass spectrometry fit into the workflow seamlessly.

Added value

- Vanquish LC systems can fit into existing software infrastructure such as Waters™ Empower™ 3 CDS software
- Method transfer tools to help maintain compliance with minimal qualifications
- Ultra-robust separation for reduction in data interpretation
- Single compliance-ready software separation for all methods of detection

Overcoming the challenges of liquid chromatography method transfer: A CDMO perspective

Seamlessly integrating state-of-the-art (U)HPLC into an existing CDS framework

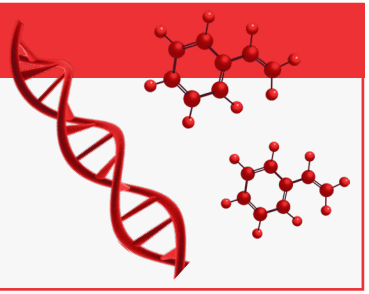
LC columns

Help us help you find the right consumable for your LC application

HPLC column selection guide

With our new LC column tool, you can now click your way to your new application. The tool guides you directly to the recommended column for your needs. Also find guard columns to prolong the lifetime of your analytical column within the tool.

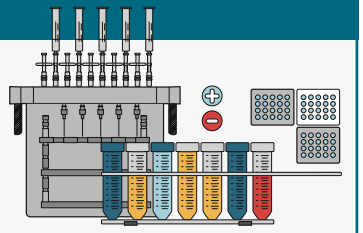
Learn more ⟶



Sample prep selection guide

Our range of sample preparation consumables ensures that your samples are prepped and ready for analysis in no time, saving you valuable lab time and increasing your throughput. Use our selection guide to find your chromatography sample preparation products and elevate your analytical capabilities.

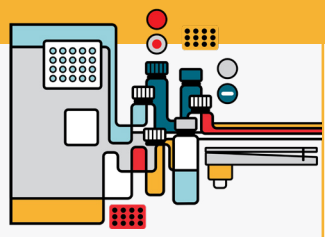
Learn more ⟶



SureSTART selection guide

Did you know that the vials that you use may impact your analysis? Luckily, now you can easily select the right vials for your application as well. Try our new Thermo Scientific™ SureSTART™ selection guide and be confident that you are using the right vial.

Learn more ⟶



Services and support

Unity™ Lab Services provides world-class service solutions to support your instruments. Our comprehensive service portfolio was designed to meet the needs of your lab.

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  - Preventive maintenance
  - Installation
- Education

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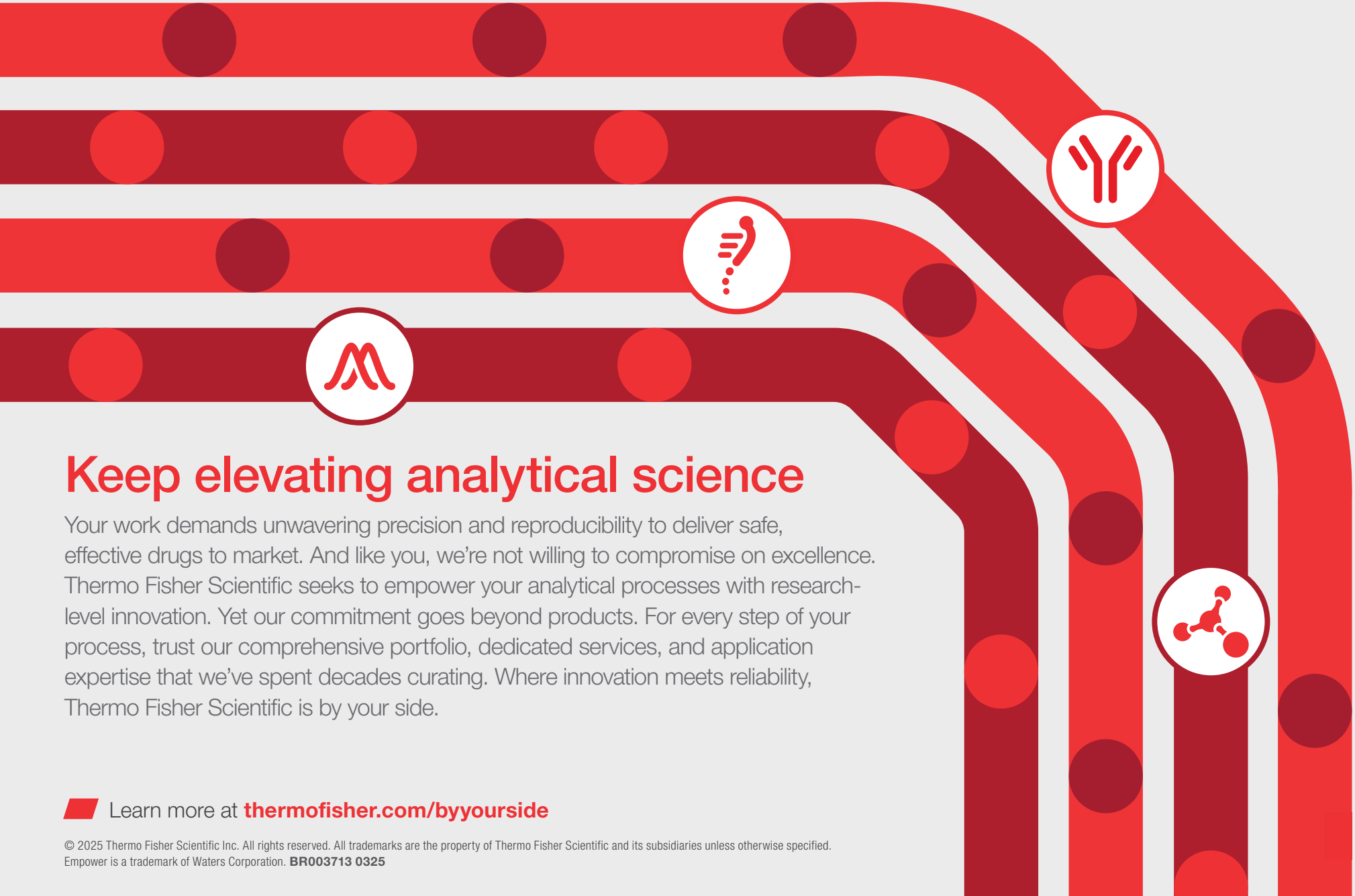

Keep elevating analytical science

Your work demands unwavering precision and reproducibility to deliver safe, effective drugs to market. And like you, we're not willing to compromise on excellence. Thermo Fisher Scientific seeks to empower your analytical processes with research-level innovation. Yet our commitment goes beyond products. For every step of your process, trust our comprehensive portfolio, dedicated services, and application expertise that we've spent decades curating. Where innovation meets reliability, Thermo Fisher Scientific is by your side.

Learn more at **thermofisher.com/byyourside**