

thermo scientific

Analytical solutions for pharmaceutical quality control testing

Enhance your capabilities



ThermoFisher
SCIENTIFIC

Analytical solutions for pharmaceutical quality control testing

Solutions for pharma QA/QC GMP testing

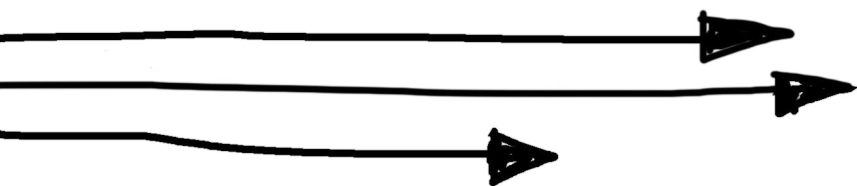
Quality control (QC) testing of pharmaceuticals must be rigorous and involves a number of analytical techniques including HPLC, HPIC, GC-MS, LC-MS, as well as elemental analysis techniques. Thermo Fisher Scientific offers a suite of analytical solutions for the monitoring and control of a number of pharmaceutical impurities, from volatiles to solids and everything in between.

Unique tools for impurity analysis

Techniques such as LC-UV can address a majority of impurity analysis needs. However, there are instances in which complementary separation or detection techniques are well suited to address a challenging analysis, such as organic acid impurities with Ion Chromatography, or being able to measure compounds that other technologies are unable to detect with Charged Aerosol Detection. We offer the most diverse technology portfolio to address your most complex analytical challenges.

Optimized impurity analysis methods

To address the evolving sensitivity requirements for low level impurities, adopting modern instrumentation and consumables can provide distinct advantages. Laboratory productivity can benefit from updating outdated legacy instruments with modern replacements that offer enhanced analytical speed and detection sensitivity. It is also common for laboratories to transfer methods between different instrument types, including those from different vendors. Method transfer is complex and relies on robust method development and validation. Adaptable instruments, able to accommodate for differences between systems, help to simplify the process.



Overview

Analytical workflows

Counterion analysis

Volatile organic & residual solvents

Semi-volatile organic impurities

Non-volatile organic impurities

Extractables & leachables

Elemental impurities

Nitrosamine impurity analysis

Technology highlights

Analytical workflows

Powerful, efficient and accurate tools are brought together to provide seamless analytical workflows purpose built to address the challenges of routine analytical testing

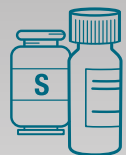
- Unrivalled technologies
- Rapid, high through-put capabilities
- Robust and reproducible methods
- Unique structural insights
- Data confidence
- Industry endorsed

Explore industry leading workflows and technology

Take a deep dive into our industry leading workflows and technology.



Counterion analysis



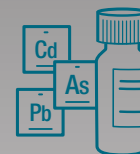
Volatile organic & residual solvents



Non-volatile organic impurities



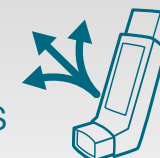
Nitrosamine impurity analysis



Elemental impurities



Semi-volatile organic impurities



Extractables & leachables

Analytical workflows



Counterion analysis

Effectively assay pharmaceutical anions and cations

Accelerate the determination and quantification of inorganic anions and cations in pharmaceutical formulations.



Volatile organic & residual solvents

Simplify your USP <467> or ICH Q3C workflows

We have proven, simple, compliant workflows for organic volatile impurities that follow regulatory guidelines.



Semi-volatile organic impurities

Unambiguous identification of organic volatile impurities

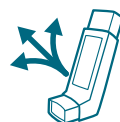
Whether you are analyzing impurities in APIs, intermediates, or excipients, our powerful workflows deliver a single identification and quantification answer with high confidence.



Non-volatile organic impurities

Identify and quantify organic impurities in drug substances and drug products

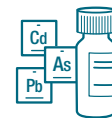
Impurity profiling is a critical quality control step in the production of pharmaceuticals and biopharmaceuticals. This process is carefully regulated and each impurity must be investigated with respect to both physicochemical and safety aspects.



Extractables and leachables

Advanced techniques for extractables testing

Extractable and leachable (E&L) testing methods demand carefully controlled extraction, analysis and identification. Our workflows can help you identify all suspects.



Elemental impurities

Perform compliant USP 232 and ICH Q3D elemental impurities analysis

We provide robust, proven workflows and instrumentation for determining elemental impurities in drugs.



Nitrosamine impurity analysis

Confidence in compliance, confidence in results

Nitrosamine impurity analysis requires robust and sensitive analytical methods to ensure confidence in the obtained results. The wide Thermo Scientific portfolio is proven to be excellent for nitrosamine analysis, ensuring your exploratory and routine methods are performed as accurately and reliably as possible while maintaining requirements from regulatory bodies worldwide.





Counterion analysis

Why determine counterions?

With more than 50% of pharmaceuticals on the market using counterions, their analysis constitutes an essential part of drug development, QC and lot release processes to ensure patient safety and drug efficacy. Salt formation is important during pharmaceutical and biopharmaceutical drug development as it enables the selective targeting of physicochemical properties such as solubility, drug stability and dissolution rates to ensure good bioavailability. In order to detect these diverse counterions, there are two commonly used analytical techniques:

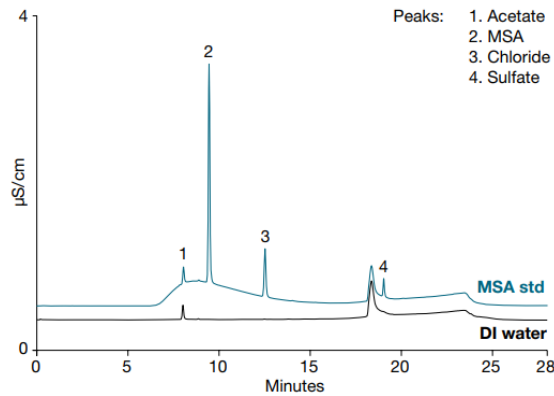
- Ion Chromatography (IC) with conductivity detection
- Ultra-High Performance Liquid Chromatography (UHPLC) with Charged Aerosol Detection (CAD) and/or UV detection

Determination of methanesulfonic acid in busulfan by ion chromatography

The proposed USP Busulfan monograph describes a Thermo Scientific™ Dionex™ IonPac™ AG11-HC guard column with L61 packing and a Dionex IonPac AS11-HC analytical column with L81 packing for the separation of MSA. The separation is followed by suppressed conductivity detection.



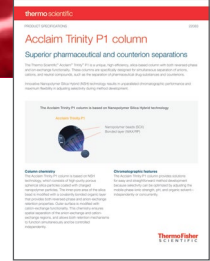
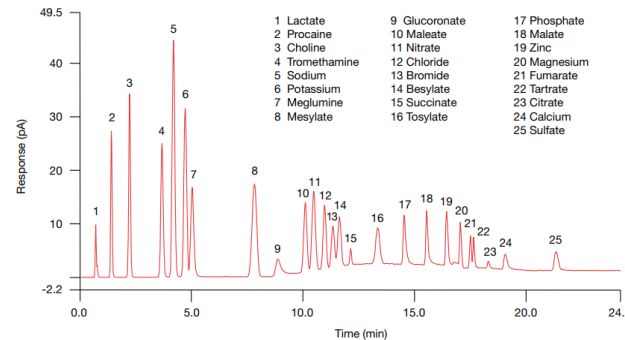
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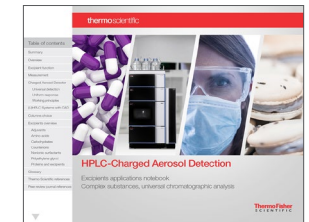
Proposed USP	Tailing factor	Peak area RSD (n=9)	Retention time RSD (n=9)	Peak height RSD (n=9)
	1.11	2.47	0.05	1.08

HPLC-Charged Aerosol Detection for excipients

Global method for measurement of anions, cations, organic and inorganic ions simultaneously utilizing charged aerosol detection for near universal response for all compounds.



View product specifications



View complete application notebook



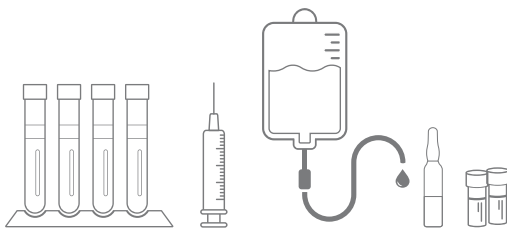
View more information about counterion analysis



Volatile organic & residual solvents

Simplify your USP <467> or ICH Q3C workflows

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, utilizing the TriPlus 500 Headspace Autosampler coupled to TRACE 1310 GC-FID.



Drug, container-closure material or single-use bioprocess material

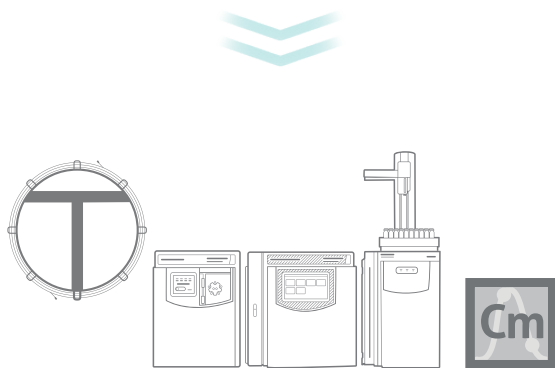


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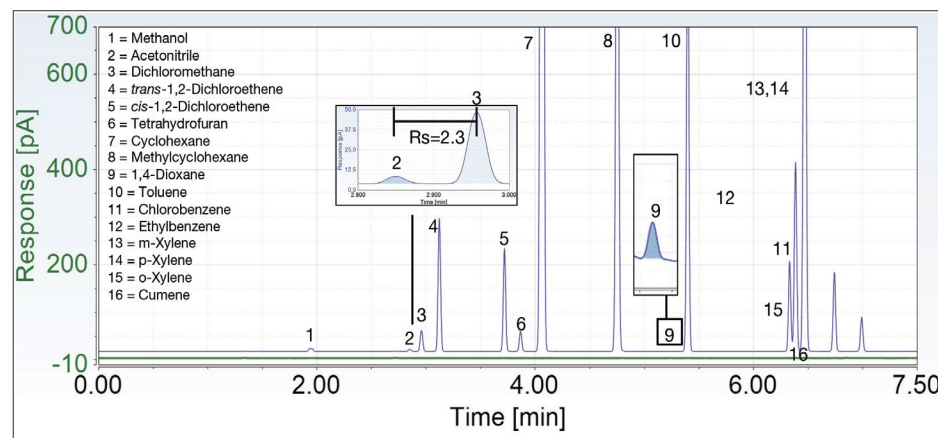


Simplified, cost-effective headspace GC method for residual solvents analysis in pharmaceutical products

Chromatographic separation for Class 2A residual solvent can be achieved in less than 8 minutes using a TG-624 SiIMS capillary column and nitrogen as carrier gas. Rs for all residual solvent peaks is ≥ 1.0 , in particular Rs between acetonitrile and dichloromethane met the regulation requirements with a calculated value of 2.3.



Valve & loop headspace GC-MS, with compliant software and method library



View more information about volatile organic & residual solvents

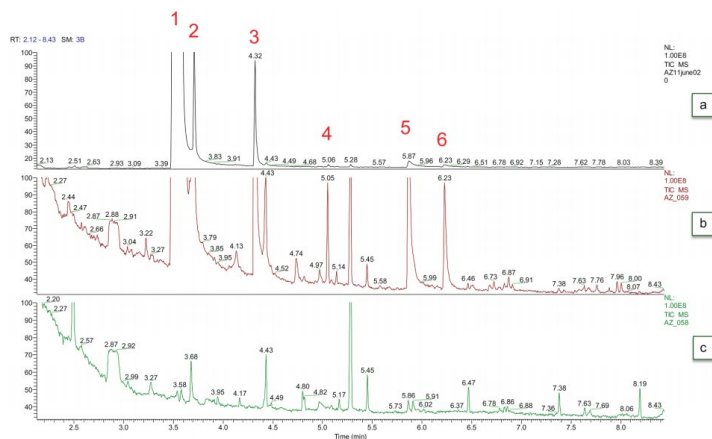
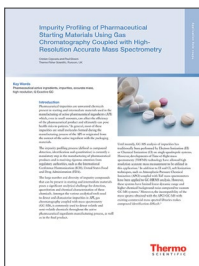
Semi-volatile organic impurities

Unambiguous identification of organic semi-volatile impurities

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. Whether you are analyzing impurities in APIs, intermediates, excipients, or extractables and leachables this powerful workflow delivers a single identification and quantification answer with high confidence.

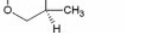
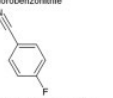
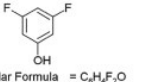
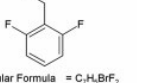
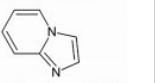
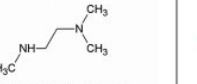
Impurity profiling of pharmaceutical starting materials using gas chromatography coupled with high resolution accurate mass spectrometry

TICs showing the (3S)-3-methylmorpholine peak at 10 µg/mL (w/v) on column (1) and several major impurities (2–6) at >0.1% level. Data acquired in full-scan EI (a) and PCI (b) using 60,000 resolution (FWHM at m/z 200). A solvent (methanol) blank injection (c) was used as a reference background. Accurate mass confirmation of the molecular ions for the samples analyzed. Data obtained from the EI was confirmed using PCI experiments. The compounds' chemical structures as well as the mass difference from the theoretical (Δ ppm) are annotated.



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Active Pharmaceutical Ingredient	Exact Mass (EI)	Measured Mass (EI)	Δ ppm	Exact Mass (PCI)	Measured Mass (PCI)	Δ ppm
(3S)-3-methylmorpholine  Molecular Formula = $C_5H_{11}NO$	101.08352	101.08358	0.6	102.09134	102.09136	0.2
4-fluorobenzonitrile  Molecular Formula = C_7H_5FN	121.03223	121.03223	0.0	122.04005	122.04012	0.5
3,5-difluorophenol  Molecular Formula = $C_6H_4F_2O$	130.02247	130.02256	0.7	131.03030	131.03032	0.2
2-(bromomethyl)-1,3-difluorobenzene  Molecular Formula = $C_7H_5BrF_2$	204.94625	204.94608	-0.9	206.96155	206.96162	0.3
imidazo[1,2-a]pyridine  Molecular Formula = $C_7H_6N_2$	118.05255	118.05256	0.1	119.06037	119.06038	0.0
N,N,N-trimethylethane-1,2-diamine  Molecular Formula = $C_5H_{14}N_2$	102.11515	102.11520	0.5	103.1073	103.12300	0.3



View more information about semi-volatile organic impurities



Non-volatile organic impurities

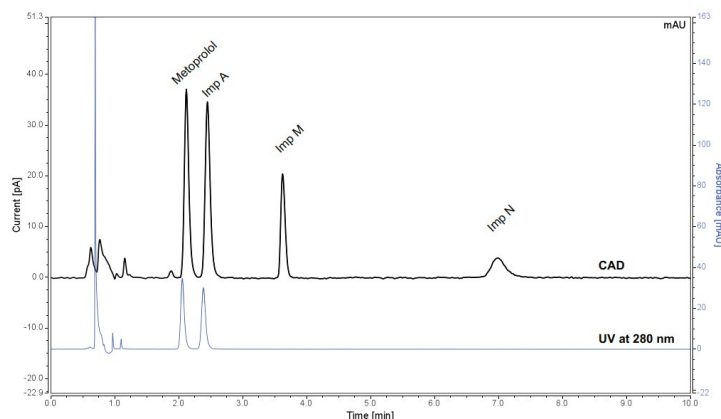
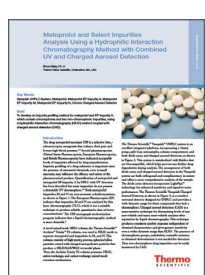
Identify and quantify organic impurities in drug substances and drug products

Impurity profiling is a critical quality control step in the production of pharmaceuticals and biopharmaceuticals. Structural characterization, quantification, and reporting must be performed using suitable analytical procedures. Impurity profiling of organic impurities is typically performed using high performance liquid chromatography (HPLC), mass spectrometry (MS). Routine and confirmatory analysis can be performed with charged aerosol detection (CAD).

Confident, unambiguous elemental composition and substructural information can be provided by our Orbitrap-based mass spectrometry systems, together with advanced informatics capabilities and libraries.

Metoprolol and select impurities analysis using a hydrophilic interaction chromatography method with combined UV and charged aerosol detection

Metoprolol and several impurities (A, M, and N) could all be separated on a novel Thermo Scientific™ Acclaim™ Trinity™ P2 column, then detected and quantified by CAD, while only metoprolol and impurity A responded on the UV detector.



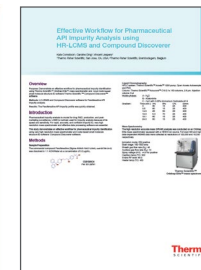
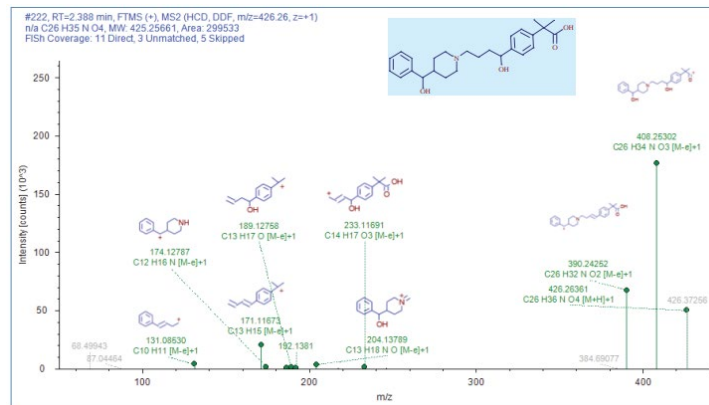
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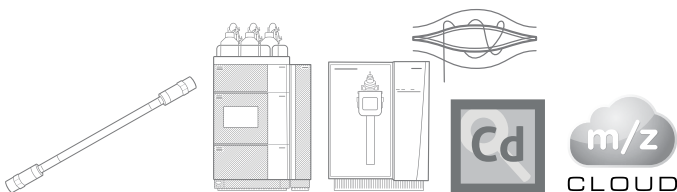
Unknown compound structure elucidation

Effective and confident impurity analysis was achieved using orbitrap mass spectrometry and compound discoverer software.

Powerful workflow options in Compound Discoverer software detect components with targeted and untargeted mechanisms, and utilize high resolution data to quickly perform fine isotope searches. The determination of the structures of impurities is simplified with automatic FISh (fragment ion search) annotations.



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Orbitrap-based LC-MS/MS with unknown identification software and online HRAM libraries



View more information about non-volatile organic impurities

Extractables and leachables

What are extractables?

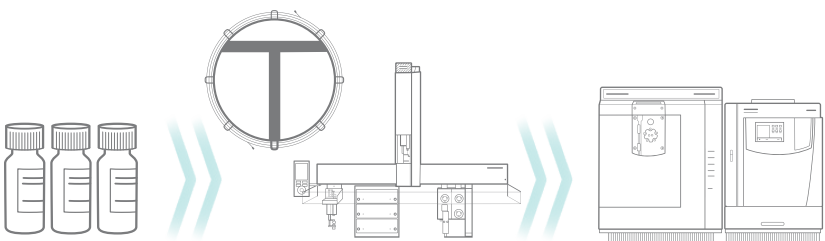
Extractables migrate from container materials when exposed under laboratory conditions to solvents under exaggerated temperature and time.

What are leachables?

Leachable are chemical species that migrate into the product under normal storage or use conditions.

Semi-volatile compounds are among the most frequently detected migration impurities

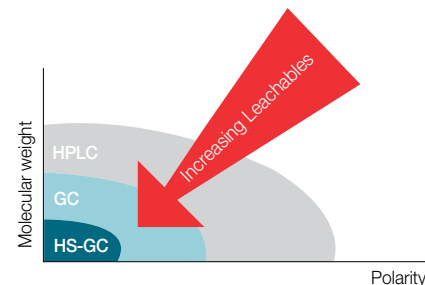
Testing is performed through liquid injection of an extract of the material or product. Often extracts are derivatized to increase analyte volatility. Testing demands absolute confidence in unknown identification and quantification.



Ultra clean Thermo Scientific™ MS Certified vials ensure the lowest backgrounds to reduce false positives

Thermo Scientific™ TraceGOLD™ GC columns and Thermo Scientific™ TriPlus™ RSH Autosampler

Absolute confidence in your analyte identification is required. Demand HRAM GC-MS with <1 ppm mass accuracy, femtogram sensitivity and 6 orders linear dynamic range.

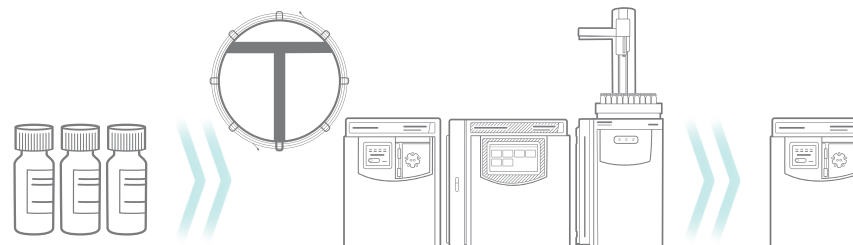


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Low molecular weight, non-polar organic compounds are typically volatile and have the highest probability to migrate from or through polymeric contact closure systems.

Testing of the contact closure material is typically conducted by headspace sampling followed by gas chromatography and mass spectrometry.



Ultraclean Thermo Scientific™ SureSTART™ headspace vials ensure low background and leak free seals

Thermo Scientific™ TraceGOLD GC columns, ISQ™ 7610 single quadrupole mass spectrometer, TRACE™ 1610 GC, and Triplus 500 HS autosampler

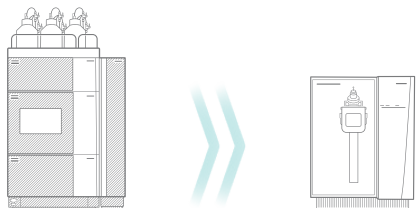
Thermo Scientific™ ISQ™ 7610 Single Quadrupole GC-MS System

View more information about extractables & leachables

Extractables and leachables

Non-volatile impurities are among the most difficult to identify.

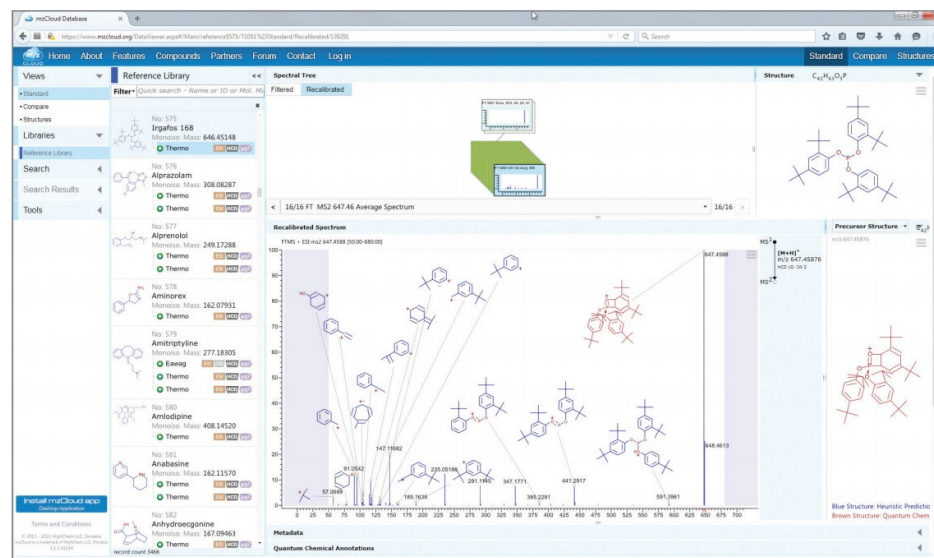
Testing is performed through liquid injection of an extract of the material or product. Often extracts are derivatized to increase analyte volatility. Testing demands absolute confidence in unknown identification and quantification.



Quick exchange ionization modes including APCI & ESI are complemented by fast polarity MS switching. Record both \pm scans within a single acquisition for complete ionization coverage. MSⁿ capabilities and exceptional mass accuracy, make the Thermo Scientific™ Orbitrap Exploris™ 120 Mass Spectrometer the perfect tool for structural elucidation of unknowns.



Thermo Scientific™ Compound Discoverer™ software ensures confident compound identification and structural elucidation with advanced algorithms that quickly process and identify changes between different sample groups and identify compounds based on multiple search approaches; including HRAM libraries, cloud based libraries like mzCloud™, and compound databases. Searches are conducted in parallel and a single unified report is delivered.



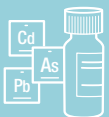
Search spectra on-line with mzCloud, a free to search online HRAM mass spectral library. Full spectral annotation with MSⁿ data, spectral trees and substructure search capabilities.



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View more information about extractables & leachables



Elemental impurities

What are elemental impurities?

Elemental impurities are traces of metals that can be found in pharmaceutical formulations resulting from catalysts, formulation ingredients, and process vessels. The analysis and control of elemental impurities is essential to mitigate any toxicological effect and preserve drug efficacy.

For over 100 years regulators have demanded the testing of heavy metal impurities in pharmaceutical products. Global regulators have issued modern revised methodologies and guidelines for monitoring a range of metal elemental impurities in pharmaceutical materials using inductively coupled plasma (ICP) optical emission spectroscopy (ICP-OES) or mass spectrometry (ICP-MS).

Analysis of elemental impurities in drug products using the Thermo Scientific™ iCAP™ PRO XP ICP-OES

The iCAP PRO XP ICP-OES delivers excellent accuracy and sensitivity for analyses of trace elements and major components in drug products.

The results obtained prove the excellent ability of the instrument to resolve complex sample spectra, and the achieved detection limits demonstrate the suitability of the instrument to analyze toxic trace elements like arsenic and mercury for which the stipulated limits are very low.

Element and wavelength (nm)	Accuracy (Recovery, n=6)	Precision (RSD, n=6)	Element and wavelength (nm)	Accuracy (Recovery, n=6)	Precision (RSD, n=6)
Cd 226.502	95.7	1.7	Rh 343.489	102.0	0.9
Cd 214.438	96.1	1.6	Rh 339.682	102.7	0.9
Pb 220.353	92.5	4.7	Ru 267.876	95.6	1.5
Pb 182.205	99.0	2.2	Ru 266.161	95.1	1.3
As 189.042	100.3	2.5	Se 196.090	105.9	2.0
As 228.812	100.9	2.8	Se 206.279	105.0	1.6
Hg 184.950	93.6	2.2	Ag 328.068	97.6	1.4
Hg 194.227	93.2	1.9	Ag 338.289	92.8	1.8
Co 228.616	95.8	1.7	Pt 203.646	97.8	0.8
Co 238.892	94.0	0.8	Pt 214.423	97.1	0.8
V 310.230	98.1	1.1	Li 610.362	93.7	2.5
V 309.311	98.6	1.2	Li 670.784	108.7	2.4
Ni 231.604	95.6	1.7	Sb 206.833	97.0	2.1
Ni 221.647	95.2	1.7	Sb 217.581	96.8	2.0
Tl 190.856	92.1	2.1	Ba 455.403	98.1	2.4
Au 242.795	98.9	1.0	Ba 493.409	94.7	3.1
Au 267.595	99.7	1.0	Mo 281.615	97.3	1.9
Pd 324.270	99.4	1.2	Mo 284.823	98.1	1.8
Pd 340.458	101.3	1.0	Cu 219.958	98.4	2.2
Ir 212.681	99.5	0.9	Cu 224.700	98.7	2.1
Ir 215.268	99.3	0.9	Sn 226.891	94.2	1.8
Os 228.226	100.1	0.7	Sn 283.999	94.7	1.9
Os 225.585	99.5	0.6	Cr 284.325	96.1	1.9
			Cr 357.869	97.2	2.1

View more about this instrument

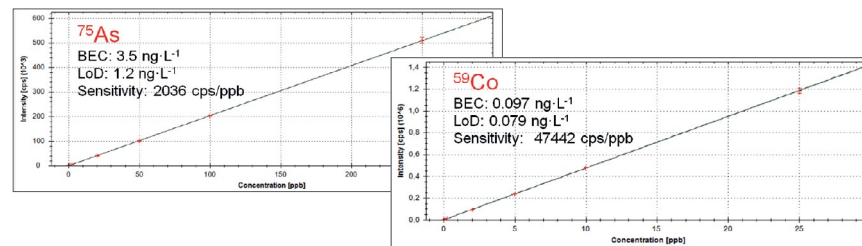
Single Mode Multi-Elemental Analysis of Traditional Chinese Medicine using the Thermo Scientific™ iCAP™ RQ ICP-MS

The iCAP RQ ICP-MS has been shown to be an excellent tool for the accurate, multi-elemental analysis of trace metals in complex samples, offering:

- A wide dynamic range (measuring $\mu\text{g}\cdot\text{kg}^{-1}$ to % levels in a single analysis).
- High instrument sensitivity.
- Freedom from interferences using a single He KED analysis mode.
- An easy-to-use workflow enabled by the Thermo Scientific™ Qtegra™ Intelligent Scientific Data Solution (ISDS).



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View more information about elemental impurities

Nitrosamine impurity analysis

Confidence in compliance. Confidence in results.

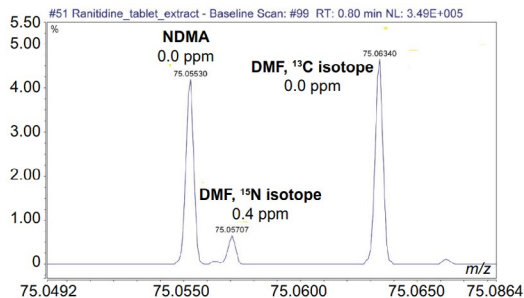
Nitrosamine impurity analysis requires robust and sensitive analytical methods to ensure confidence in the obtained results. The wide Thermo Scientific portfolio is proven to be excellent for nitrosamine analysis, ensuring your exploratory and routine methods are performed as accurately and reliably as possible while maintaining requirements from regulatory bodies worldwide.

GC-MS and LC-MS methods for the determination of nitrosamine impurities in pharmaceuticals drugs

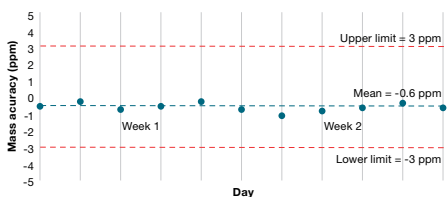
Remove all uncertainty with Orbitrap-based detection capable of easily distinguishing from target analytes and isobaric matrix components.



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Baseline mass resolution between NDMA and ¹⁵N isotope of DMF, a common solvent impurity, only 0.008 Da mass different.



Example data showing (A) ¹³C-NDMA-d6 ppm mass error with upper and lower limits 3 ppm.



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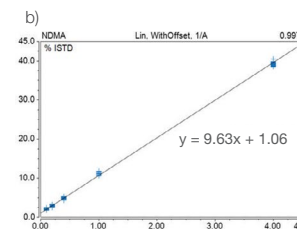
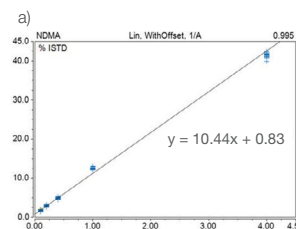


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Highly sensitive and robust LC-MS/MS solution for quantitation of nitrosamine impurities in metformin drug products

Calibration lines at the front and back of a 1000 injection batch. Redefine robustness with combination of separation, consumables and detection combining to produce world beating performance, reducing downtime and improving lab efficiency.



View complete application note



Register for nitrosamine analysis webinar series
See our latest webinars on nitrosamine analysis including detection of pre-cursors, fast routine monitoring and laboratory automation for increased productivity.



View more information about nitrosamine impurity analysis

Technology highlights

Unrivalled technology enables robust operation and reliable data from every sample

Learn more about the technology



Liquid chromatography



LC-MS



Charged aerosol detection



Ion chromatography



GC-MS



ICP-MS



Consumables—
vials, septa, columns and more



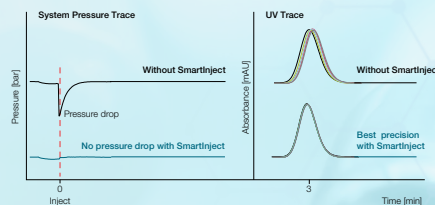
Powerful and intuitive software



Dependable, flexible, and productive liquid chromatography

Thermo Scientific™ Vanquish HPLC and UHPLC systems are the most advanced liquid chromatography instruments available.

The Vanquish LC platform improves performance, repeatability, and dependability with no trade-offs in quality or ease-of-use.



Enhanced retention time reproducibility and longer column lifetime due to novel SmartInject Technology



[View full brochure](#)

Thermo Scientific™ Vanquish™ Core HPLC Systems Simple to the CORE

Eliminate disruptions to your routine analytical work with the Thermo Scientific Vanquish Core HPLC system. No matter which systems you currently use, switching to Vanquish Core is simple and seamless. A full suite of method transfer tools, including tuneable gradient delay volume, makes adoption easy. Like all members of our Vanquish product line, Vanquish Core HPLC systems offer hardware precision, detector sensitivity, and simplicity of operation

- Simplified method transfer
- Intelligent system tools
- Easy and reliable tool-free connection
- Versatility in analyte detection. Simple integration with your Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS), Waters™ Empower™ 3 CDS and Agilent™ OpenLab™ CDS software



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[Build my Vanquish system](#)

Thermo Scientific™ Vanquish™ Flex UHPLC Systems Easier method development and routine analysis

For assays that require more flexibility to accommodate all applications, the Thermo Scientific Vanquish Flex UHPLC systems enable you to increase your productivity and drive innovation without compromising quality. Whether you need an LC or LC-MS solution, the flexibility of the Vanquish Flex systems with binary or quaternary solvent blending provides the most advanced performance through better separations, more results and easier interaction.

- Unparalleled flexibility to meet all needs of routine HPLC and UHPLC applications
- Fast, automated, and comprehensive method development
- Full biocompatibility to address the most challenging biotherapeutic applications
- Simple integration with your Chromeleon CDS, Waters™ Empower™ 3CDS and Agilent™ OpenLab™ CDS software



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Enabling precise quantitation and structural elucidation with high resolution mass spectrometry

The next generation Thermo Scientific LC-HRAM systems deliver on ease without sacrificing high performance.

A unified instrument architecture enables same performance accessories between systems, facilitates easier method transfer, and accelerates familiarization for new users. Intelligence-driven systems enables the highest quality mass spectrometry data for increased confidence. Pre-defined experimental conditions enables simplified user access and simplicity of operation. Streamlined data processing software, algorithms, and libraries address the most challenging research and routine applications.



Thermo Scientific™ Orbitrap™ Exploris 120 mass spectrometer

The new standard in productivity—the proven Orbitrap technology

- Accelerates your route to qualitative and quantitative confidence for both method development and everyday testing purposes.
- Unique ability to provide consistently accurate data
- Design made for operational simplicity
- Sets the new standard in instrument productivity and ruggedness

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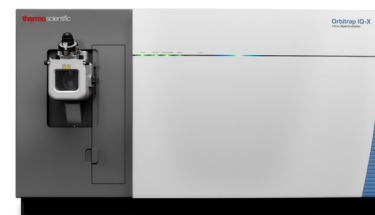
Thermo Scientific™ Orbitrap™ Exploris 240 mass spectrometer

Deliver the exceptional—deliver on your objectives

- Combines application flexibility with the performance to drive discovery and identification
- Quantitative precision and accuracy you need to confidently scale up and achieve impact
- Operational simplicity through intelligent data acquisition and processing
- Fast track to confident results regardless of sample complexity, depth of insights required or the presence of unknown compounds

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Thermo Scientific™ Orbitrap™ IQ-X™ Tribid™ mass spectrometer

Go beyond for small molecule analysis

- Designed to reveal complex chemical structures for compound identification and structure elucidation of small molecules. Combines industry-leading mass analyzer technology with intelligent automation
- Intuitive software, and remote, hands-free calibration
- Identification and characterization so you can confidently collect more meaningful data

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Fast and sensitive robust quantitation with triple quadrupole mass spectrometry

Confident quantitation with triple quadrupole LC-MS systems

From addressing complexities of molecules and matrices, to ensuring ease-of-use while satisfying regulatory requirements—today's challenges in targeted quantitation involve more than just measuring concentrations of target analytes. Achieve ultimate confidence in your data quality with a robust, sensitive, reproducible, and reliable targeted quantitation method using our new liquid chromatography mass spectrometry (LC-MS) workflow solutions.



Thermo Scientific™ TSQ™ Fortis mass spectrometer

For a new level of confidence

Maximum productivity distinguishes the TSQ Fortis Triple Quadrupole MS from the competition.

- Enhanced dual-mode discrete-dynode electron multiplier detector
- Ion beam guide with neutral blocker
- Active collision cell with axial DC field

Its robust design ensures reliable and consistent results, whether the methods are single sample-based experiments or high-volume screenings and quantitations.

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Thermo Scientific™ TSQ™ Quantis mass spectrometer

Confident quantitation for everyday excellence

Simplify everyday quantitation with the TSQ Quantis Triple Quadrupole MS, which offers outstanding robustness and sensitivity

- Segmented quadrupoles
- Enhanced dual-mode discrete-dynode electron multiplier detector
- High-resolution SRM (0.4 FWHM)

The TSQ Quantis meets every targeted quantitation workflow requirement, with an ease-of-use that ensures quality data.

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Thermo Scientific™ TSQ™ Altis mass spectrometer

Achieve ultimate sensitivity and robustness without compromise

The TSQ Altis Triple Quadrupole MS meets tomorrow's needs today.

- Segmented quadrupoles with hyperbolic faces
- High resolution SRM (0.2 FWHM) for unprecedented sensitivity, selectivity, and speed

The TSQ Altis enables every analytical laboratory to successfully address its most demanding applications.

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Easy and robust mass spectrometry

Gain more confidence and invest in your lab's future with single quadrupole and linear ion trap mass spectrometry

MS provides sensitivity and selectivity for your analyses, giving you more insight into your samples and ability to resolve difficult separations, including co-eluting peaks, using differing mass-to-charge (m/z) ratios. Our single quadrupole MS systems set new standards for robustness and ease-of-use. They are built for every day, reliable routine operation with seamless integration into your HPLC or UHPLC system.



Thermo Scientific™ ISQ™ EC single quadrupole mass spectrometer

Access value that only MS can provide

Add mass spectrometry (MS) to your IC and LC analyses for access to the valuable data that only MS can provide.

- Easy-to-use and seamlessly integrates with chromatography systems
- Both novices and experts alike can quickly master MS
- Gain more confidence and insights from every sample

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Thermo Scientific™ ISQ™ EM mass spectrometer

Gain more insights

The easy-to-use ISQ EM Single Quadrupole MS seamlessly integrates with LC systems for reliable, robust, and easy LC-MS routine analysis

- Extended mass range for more flexibility
- Detect and quantify a variety of analytes by choosing to use either heated electrospray ionization (HESI) or atmospheric pressure chemical ionization (APCI)

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Overview

Analytical workflows

Counterion analysis

Volatile organic & residual solvents

Semi-volatile organic impurities

Non-volatile organic impurities

Extractables & leachables

Elemental impurities

Nitrosamine impurity analysis

Technology highlights

Universal, near-uniform response with charged aerosol detection

Obtain sensitive, universal detection with a near-uniform response

Charged aerosol detectors measure a wide range of analytes in the areas of pharmaceuticals (large and small molecule), biomolecules, foods and beverages, specialty chemicals, and polymers. Their flexibility and performance are ideal for analytical R&D, while the detectors' simplicity and reproducibility benefit manufacturing QA/QC applications.

Thermo Scientific™ Vanquish™ Charged Aerosol Detector

Detect and quantify virtually any substance using the near-universal detection capabilities of Vanquish Charged Aerosol Detectors. With enhanced linear dynamic range and accurate, consistent response, this detector can measure low-level impurities and active pharmaceutical ingredients (APIs) simultaneously, as well as other compounds, regardless of chemical structure.

No other UHPLC detector available today can match the all-around performance of the Vanquish charged aerosol detector. It can be used for the analysis of:

- Pharmaceuticals
- Natural products
- Carbohydrates
- Polymers
- Surfactants and excipients
- Macromolecules

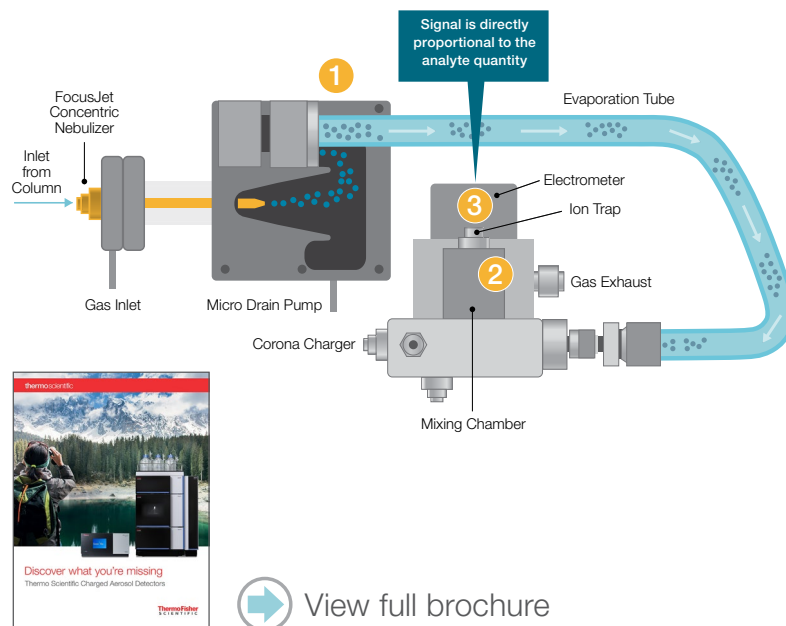


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Charged aerosol detection bibliography

See how other labs use this novel detection method

Charged aerosol detection has the ability to measure any non-volatile and semi-volatile analytes at sub-nanogram levels, and does not require ionization or a chromophore. This bibliography highlights the breadth and scope of different analytical methods found in the literature.



Charged aerosol detection measures charge not analytes

Schematic of CAD technology

1. Nebulization
2. Charging
3. Detection



[View full brochure](#)

Separate your productivity from the status quo with high quality optical detectors

Flexibility, robustness, and performance as standard

Confidently detect the analytes in your sample with the wide array of detectors available for the Thermo Scientific Vanquish HPLC and UHPLC systems. Our portfolio includes a variety of optical detectors: UV-Vis absorption detectors, fluorescence detectors and refractive index detectors.

Thermo Scientific™ Vanquish™ Diode Array Detectors and Multiple Wavelength Detectors

The Thermo Scientific Vanquish Diode Array Detector FG is designed for the highest reliability and flexibility with a wide portfolio of flow cells to match your application needs. The Diode Array Detector FG offers excellent linearity and optimized noise performance to support a wide dynamic range and low limit of detection.

[View advantages of Vanquish Diode Array Detector FG](#)



Thermo Scientific™ Vanquish™ Fluorescence Detector

Get trace detection performance through highly effective stray light suppression with Thermo Scientific Vanquish Fluorescence Detectors. These detectors reduce thermal effects using temperature-controlled flow cells for increased detection precision. Monitor up to four wavelength pairs simultaneously, or scan your chromatogram for the best emission/excitation wavelengths. Improve detection sensitivity and selectivity by leveraging ultrafast wavelength switching between peaks.

[View advantages of Fluorescence Detectors](#)

Innovative ion chromatography systems for every performance requirement

Your ion chromatography system should meet the demands of your analyses, while still fitting within your budget.

Whether you need a robust IC system for routine analysis or a flexible, modular system for more demanding analyses, we have what you need. Our IC systems include low-cost, high-pressure, capillary, and modular options for every analysis requirement. Thermo Scientific Dionex IC systems allow you to overcome any challenges in ion analysis to obtain reliable results, faster and easier.

Thermo Scientific™ Dionex™ Integrion IC system

The Dionex Integrion IC makes ion chromatography virtually automatic. Just add water to the system and Integrion does the rest because it will generate your eluent and automatically take care of counterion suppression. Integrion is versatile for analyzing environmental contaminants, sugars and simple carbohydrates in food and beverages, ionic compounds in pharmaceuticals and ions of concern in industrial and petrochemical applications. This small integrated system can also be upgraded as your lab's needs change.



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Thermo Scientific™ Dionex™ IC-6000 IC system

The Dionex ICS-6000 is designed to perform complex ion chromatography analysis, from routine QC/QA analyses to cutting edge research as well as trace analysis. A highly flexible ion chromatography system provides you with the freedom to develop, explore, and run different methods simultaneously. The ICS-6000 can run any IC application.



[View more about this instrument](#)

Sensitive, reproducible results for the most challenging GC-MS applications

Our gas chromatography-mass spectrometry systems offer ultimate performance while consistently producing trusted qualitative and quantitative results.

Extract more information from every sample and increase the confidence of your analytical results. Combined with productivity enhancing software, our advanced GC-MS instruments enable you to meet or exceed the most stringent requirements for performance, reliability, and value. Browse our complete portfolio or let one of our experts help you tailor a selection specific to your application and workflow needs.



Thermo Scientific™ ISQ™ 7610 single quadrupole GC-MS

Unstoppable productivity and performance

Discover the selectivity and confidence provided by mass spectral data with a Thermo Scientific ISQ 7610 single quadrupole GC-MS system. Our easy-to-use system can be implemented for a wide range of GC applications and methodologies and ensures productivity for food, environmental and forensic toxicology testing.

[View more about this instrument](#)



Thermo Scientific™ TSQ™ 9610 triple quadrupole GC-MS

The benchmark for high throughput labs

Combine superb sensitivity and selectivity with outstanding reliable productivity with a Thermo Scientific TSQ 9610 triple quadrupole GC-MS/MS system. This system is the go-to instrument for sensitive and specific quantitation of target compounds.

[View more about this instrument](#)



Thermo Scientific™ Orbitrap™ Exploris GC Transform your GC-MS results

Get superior quantitative and qualitative GC-MS performance with Thermo Scientific high-resolution accurate mass (HRAM) GC-MS systems. Our Orbitrap mass analyzer mass spectrometers offer unparalleled performance, sensitivity and dynamic range for the most challenging applications.

[View more about this instrument](#)
 [View more about High-Resolution Accurate-Mass GC-MS](#)

Robust instrumentation for determining elemental impurities in drugs

Perform compliant USP 232 and ICH Q3D elemental impurities analysis

Elemental impurities in pharmaceutical formulations can interfere with drug efficacy or have a toxic effect on the patient. Regulators have issued guidelines—such as ICH Q3D, USP 232 and USP 233 Elemental Impurities—for monitoring a range of metal elemental impurities in pharmaceutical materials using inductively coupled plasma (ICP), atomic absorption spectroscopy (AAS), or mass spectrometry (ICP-MS).



Thermo Scientific™ iCAP™ RQ ICP-MS

Expand your analytical capabilities with this complete trace elemental analysis solution for your high-throughput lab. User-inspired hardware and software combine to deliver maximized productivity and robustness. Simplicity and ease-of-use work in concert to streamline workflows and achieve 'right-first-time' results; essential to all busy labs.



Thermo Scientific™ iCAP™ PRO XP ICP-OES

Ensure that your lab is ready for any challenge with the powerful, multi-element capability of the Thermo Scientific iCAP PRO Series ICP-OES system. Produce consistent, reliable data quickly and easily. Experience enhanced sample throughput, matrix tolerance, and flexibility to produce results you can trust.



Thermo Scientific™ iCE™ 3500 AAS Atomic Absorption Spectrometer

Unrivalled performance, flexibility and simplicity. The innovative dual atomizer design enables safe, software-controlled switching between flame and furnace analysis with a single mirror movement. The high precision, double beam optics, combined with an Echelle monochromator produce low detection limits and long term analytical stability. Unique Quadline deuterium background correction with guaranteed performance is provided as standard.

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Quality consumables you can rely on for dependable results



Liquid chromatography

With over 40 years as a leader in LC column technology, the Thermo Scientific™ HPLC and UHPLC family of products offers a variety of particle sizes and column designs to meet all separation needs, including improved resolution, enhanced sensitivity, faster analysis and consistent performance.

- Reversed-phase columns
- Normal phase columns
- HILIC columns
- Mixed-mode columns
- Ion-exchange columns
- Size-exclusion columns
- Application specific columns

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Ion chromatography

You'll find a complete line of columns for hydroxide, carbonate, and methanesulfonic acid (MSA) eluents. Many are now available with our newest innovative formats. Our BioLC columns, the Thermo Scientific™ Dionex™ AminoPac™ and CarboPac™ columns, enable direct analysis of amino acids and carbohydrates by IC.

- Hydroxide-selective anion exchange
- Ion-exclusion IC columns
- Carbohydrate eluent anion exchange
- Amino acid IC columns
- Carbohydrate IC columns
- Cation exchange columns
- Reverse phase columns
- IC concentrators columns
- IC Trap columns

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Gas chromatography

Our columns represent a leap forward in performance, delivering low bleed and superior inertness. Select from our comprehensive portfolio of Thermo Scientific GC columns that meet all of your analytical needs and achieve reliable, reproducible results.

- Application specific columns
- Non-polar GC columns
- Low-polar GC columns
- Mid-polar GC columns
- Polar GC columns
- PLOT GC columns
- Ultrafast GC columns

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Vials and closures

Autosampler vials and compatible inserts, septa, and closures designed for chromatography applications. Products come in various dimensions, material compositions, volume capacities, closure types, and colors. Products are available as individual components or kits.

- Screw top vials and kits
- Crimp top vials and kits
- Head space vials and kits
- Certified vial kits
- Micro vials and inserts
- 96 and 384 well plates
- Electronic crimpers and decrimpers
- Manual crimpers and decrimpers

[View more information on Thermo Scientific™ SureSTART™ vials and caps](#)

Take control of the integrity of your data, from acquisition to processing



Thermo Scientific™ Chromeleon™ Chromatography Data System (CDS) Software

Streamline your laboratory workflows using Chromeleon CDS. Built with both the lab and IT in mind, this software delivers superior compliance tools, networking capabilities, instrument control, automation, data processing, and much more. It's a full enterprise solution designed for tracking, accountability, and QA/QC that is incredibly easy to use, with fewer mouse clicks, and more "right-first-time" results. It's also designed to scale globally and provide strong, reliable return on investment. Chromeleon CDS is the bottom-line decision your lab will love you for.

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Thermo Scientific™ Compound Discoverer™ Software

Streamline and customize high-resolution accurate-mass data analysis with Thermo Scientific Compound Discoverer small molecule identification software. Compound Discoverer simplifies and reduces processing clicks, enabling you to go from analysis to insight faster. Fully customizable node-based workflows, integrated compound identification capabilities, and statistical analysis streamline data analyses to deliver confident results to drive your decision making.

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Thermo Scientific™ Qtegra Intelligent Scientific Data Solution™ (ISDS) Software

Discover the Thermo Scientific™ Qtegra ISDS™ Software platform, used to enable the analysis of elements and isotopes. Qtegra ISDS Software streamlines and automates your workflow, enables extensive control for optimizing analytical conditions, and provides the flexibility required for the most demanding applications.

 [View more](#)



mzCloud™ Mass Spectral Library

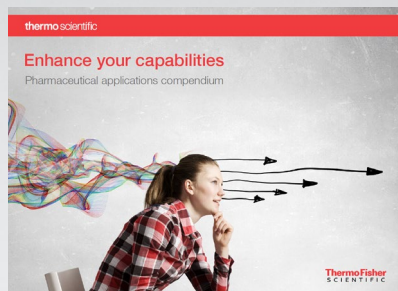
Mass spectral libraries and databases may be required to identify unknown compounds when reference standards are not available. This is particularly true for studies in areas such as metabolomics, forensic toxicology, food & beverage, environmental emerging contaminants or extractables & leachables. In these situations, a mass spectral library, particularly a high-resolution and accurate-mass MSⁿ fragmentation library, such as the mzCloud mass spectral library, can provide the information required to confidently identify unknown compounds.

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Enhance your capabilities...as your partner, Thermo Fisher Scientific provides all the right products and solutions for your pharmaceutical control challenges with exceptional separation, reproducibility, and high-quality data providing seamless operation in a compliance-ready data environment.

Dependable technologies for quality control

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Discover the latest nitrosamine solutions

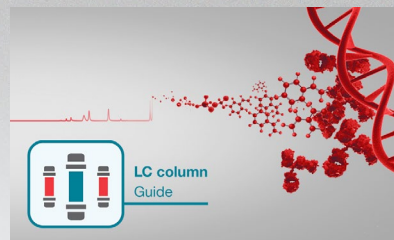
No matter which route you choose for nitrosamine and their precursor analysis we have all options covered.




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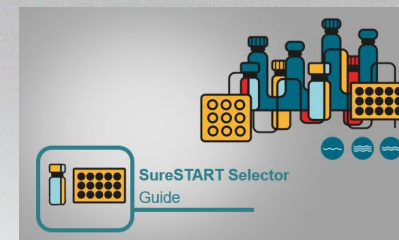
Helpful tools selecting columns, vials, caps, and wellplates


This LC column selection guide is an easy-to-use tool that ensures you find the right LC column for your experimental requirements.



 Try the tool

The Thermo Scientific™ SureSTART™ selection guide has made selecting your vial and well plate easier than ever.



 Try the tool

Stay up-to-date

Register for our pharma community email to hear about the latest advances in pharmaceutical testing.

 Join the pharma community



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