thermo scientific

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엠 · 씨 · 아이 · 케이 주식회사
MATERIAL CHARACTERIZATION INSTRUMENTS, KOREA

Safely accelerating drug development for brighter outcomes

A complete range of spectroscopy and materials characterization tools

ThermoFisher SCIENTIFIC

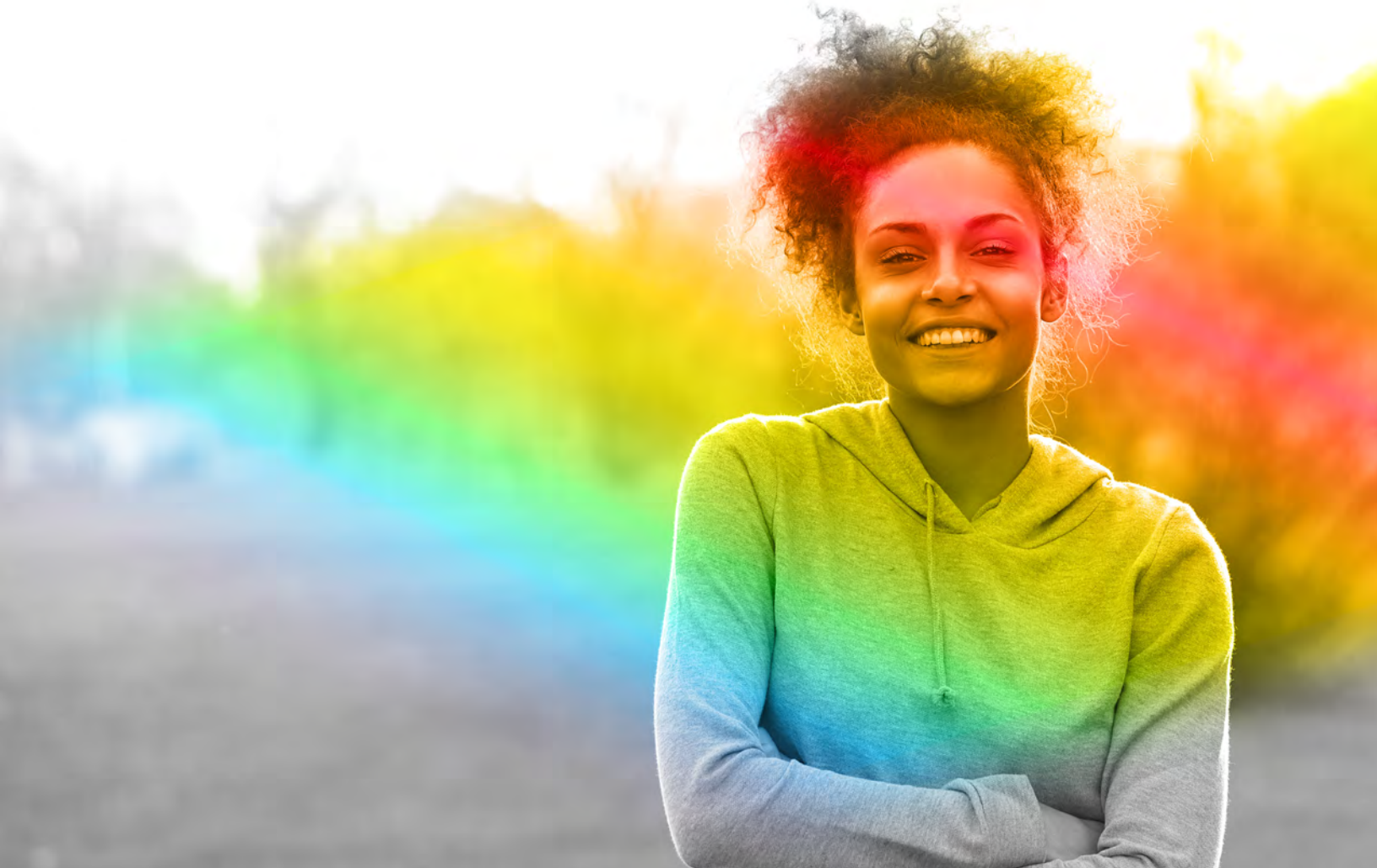
Thermo Fisher Scientific offers a wide range of spectroscopy instruments and software, extrusion and rheological tools, and service and support, enabling pharmaceutical labs to assure quality and product safety while meeting regulatory compliance throughout the drug development and formulation processes.

Developing safe drugs by chemical and biological methods must meet stringent quality and regulatory requirements. The Thermo Scientific spectroscopic and extrusion portfolio supports the research work and enables quality and regulatory compliance throughout the drug formulation, development, and manufacturing processes. Our experienced team works as your pharmaceutical lab partner to always support your efforts with our latest spectrophotometers and software to ensure compliance with the latest regulatory requirements.

In addition to spectroscopy and materials characterization tools, we offer solutions in:

- Bioproduction
- Chromatography and mass spectrometry
- Assays, media, and other consumables for drug discovery research
- Services and support for drug development, clinical trial logistics, commercial manufacturing
- Clinical research

Inside



A comprehensive array of instruments

Our comprehensive portfolio includes X-ray plasmon spectroscopy (XPS), energy-dispersive spectroscopy (EDS), Raman, Fourier-transform infrared (FTIR), near-infrared (NIR), X-ray diffraction (XRD), rheometers, and ultraviolet-visible (UV-Vis) spectroscopy. Using our state-of-the-art instruments ensures quality control across all steps and phases of your workflow and provides drug product consistency from initial formulations to large-scale production, employing fast, non-destructive methods. Thermo Scientific Pharmaceutical Extruders allow drug formulation labs to produce consistent API dispersion from initial research through clinical trials and production, with three different sizes of twin-screw extruders that offer the hot melt extrusion (HME) and wet granulation (twin-screw granulation or TSG) capabilities. When you need additional help, our services and support teams can provide repair of critical instruments and after-sales service and support.

Data security to meet compliance requirements

When it comes to software, you can confidently secure your laboratory data and ensure it meets data security regulations with our latest software solutions. Thermo Scientific Security Suite Software can be coupled with several of our analytical software tools to provide the data integrity needed to meet 21 CFR Part 11 regulations for electronic documents. The Thermo Scientific™ SolstiX™ XRD Software with Security Suite package is available with our complete ARL™ EQUINOX XRD range and also enables 21 CFR Part 11 compatibility. Many of our instruments let you take advantage of integral compliance solutions in the instrument software (for example, the Thermo Scientific Evolution™ 350 UV/Vis Spectrophotometer includes 21 CFR Part 11, USP, and PHEUR compliance). The Thermo Scientific Nicolet™ Summit FTIR Spectrometers, NanoDrop™ One UV-Vis, Evolution UV-Vis, and ARL EQUINOX XRD systems all support validated configurations for pharmaceutical QA/QC that meet the stringent 21 CFR Part 11 requirements. Thermo Scientific OMNIC™ Paradigm Software collects data, analyzes samples, and creates workflows. All spectral data is stored in a database, which provides more data storage flexibility and security. Many of these software solutions offer traceability with complete audit trails, always ensuring the integrity of your data throughout its life cycle.







Twin-screw Extrusion	Raman	FTIR	NIR	XRD	Rheometry	UV-Vis
Enhancing bioavailability and enabling continuous granulation	Chemical compound identification Identification of both organic and inorganic materials	Chemical compound identification Identification of organic materials in bulk state	Chemical compound identification QA/QC and process control	Crystalline phase identification and amorphous content determination	Characterization of fluid properties and other complex materials	Quantitative measurements of reflection or transmission properties of a material

From research to production, Thermo Fisher Scientific enables pharmaceutical labs to produce safe and effective drugs that meet stringent regulatory requirements. By providing a comprehensive spectroscopy and materials characterization tool set, intuitive data analysis software, and one of the industry's largest service and support organization, we help drug producers ensure quality from start to finish.

Comprehensive, full-spectrum support

When you choose instrumentation from Thermo Fisher Scientific, you enter a partnership with an experienced team who you can count on to assist you throughout the workflow, with comprehensive, worldwide application support and training, after-sales customer service, instrument compliance solutions, and a global, world-class support network. We can leverage the collective experience of our entire organization to help you successfully navigate the drug discovery and development environment to discern, evaluate, and gain regulatory approval for marketing a drug product. We are here to support you along the complex pathway, no matter how challenging, from R&D through preclinical studies and clinical trials to review and approval of a commercial product.

Unique capabilities

How do the Thermo Scientific spectroscopic analytical instruments and services enhance the pharma/biopharma workflow? Our instruments deliver reliable, stable performance with utmost reproducibility. Our team can help you select, use, and service your tools to ensure drug quality, safety, and speed to market. When coupled with cutting edge software, your instrument can capture data needed throughout the workflow to meet quality needs, GMP guidelines, pharmacopoeia (USP and EP) requirements, 21 CFR Part 11 compliance, and create the reports needed for regulatory filings. Each qualified installation, in cooperation with world-class technical service and support experts, sets the stage for a successful journey through the workflow. The technology and method that you choose can help you realize unleashed analytical benefits at each stage of the process:

Technology	Benefit example
FTIR	• Contaminant identification • Identify molecular polar substructure • Couple with Raman to assess molecular structure and stereochemistry
NIR	• Inline monitoring of extrusion process • As a process analytical tool (PAT), allows real-time monitoring of product quality attributes to help deliver a constant desired product quality • Final product quality control in QC lab
Raman	• Can map areas of a sample (e.g., tablet) to screen for component distribution or contamination • Reveal subtle structural and orientation differences in molecules • Facilitate quantitative analysis at micro levels
UV-Vis	• Minimize sample handling • Assess concentration and purity in small or large molecule formulations • Micro UV spectrometry offers a large dynamic range to eliminate dilution
Rheometry	• Measure critical rheological properties of compounds and extrusions • Use with polarization microscopy to study crystallization behavior to manage compounding and extrusion • Efficiently screen delivery parameters
XRD	• Ensure product safety with the ability to assess polymorphs and amorphous content • Speed up analysis time for organic samples • Measure samples in reflection or transmission mode in the same configuration
HME	• Enhance drug characteristics, including solubility enhancement, drug stability, consistent API dispersion, taste-masking, specialized dosing forms, and reformulation • Shorten the path from feasibility studies to production • Enable easy implementation of in-line monitoring, reduction of offline sampling, and minimization of reagents and disposables
TSG	• Facilitates implementation of continuous manufacturing • Use the hybrid mode to run HME and TSG
Software solutions	• State-of-the-art software with a dedicated development team following updates in regulations requirements, full audit trails • Unified data security suite across product lines • Homogenized IT administrative tasks with a common security framework

Solutions for scaling up and partnering instruments

Whether you're just starting or ready to progress from pilot scale in **Research & Discovery** to the small-to-medium scale batches needed in **Development** and **Clinical Study** phases and ultimately to commercial scale **Manufacturing** with continuous processes, our team of pharmaceutical experts will help you achieve your product development goals and choose the right instrument for your workflow. For granulation and extrusion, our support experts can help you make the best choices on size and compatibility with upstream and downstream processes to meet your formulation needs early, midway, and at the production stage.

When you're working at the feasibility studies phase, the Thermo Scientific™ Pharma *mini* HME Micro-Compounder can perform a quick and early assessment of new API/excipient formulations and helps identify drug candidates for hot melt extrusion by compounding as little as three grams of material. Then, when you're ready to scale up, especially if you have a promising new API that cannot otherwise be solubilized, Pharma 11, Pharma 16, and Pharma 24 twin-screw extrusion technology can get you over that obstacle. And finally, when you're ready to streamline manufacturing, we can help you seamlessly integrate in-line analysis equipment and accessories upstream (like feeders) and downstream (like dryer, coating, and forming technology) for an optimized, continuous production process.

Twin-Screw Extruders	Pharma *mini* HME	Pharma 11	Pharma 16	Pharma 24
Recommended for	• Feasibility • Small-scale HME • Implants (ophthalmic and injectable)	• Research and discovery • Laboratory scale	• Development pilot scale • Production scale	• Manufacturing • Production scale
Suitable for	• Co-extrusion • Implant production	• Co-extrusion • Sheet extrusion • Implant production	• Co-extrusion • Sheet extrusion • Implant production	• Sheet extrusion • High-volume HME production
Downstream options	• Take off belt	• Conveyor belt • Pelletizer	• Conveyor belt • Pelletizer • Chill roll	• Conveyor belt • Pelletizer • Chill roll
Typical throughput HME**	3 g batch or 100 g/h	20 g/h – 2.5 kg/h	0.5 kg/h – 10 kg/h	1 kg/h – 30 kg/h
Typical throughput TSG**	*	Up to 3 kg/h	Up to 20 kg/h	Up to 80 kg/h
Unit type	Benchtop model	Benchtop model	Floor model	Floor model
Screw design	Conical, co-/counter-rotating	Parallel, co-rotating	Parallel, co-rotating	Parallel, co-rotating

* No TSG option
* Depending on formulation
* All parallel screw designs are interchangeable between HME and TSG operation

All extrusion instruments are made of pharma-grade steel and allow you to meet GMP compliance standards.

The workflow

Research and Discovery	Development	Clinical Study	Manufacturing
Identify & validate target of interest and identify leads	Advance a lead through testing, formulation & synthesis scale-up	Experiment & observe to generate safety & efficacy data	Industrial-scale synthesis of pharmaceuticals
FTIR, LC-MS, Micro UV, Raman, SPM, UV-Vis, XRD	FTIR, HME, NIR, Raman, TSG, XRD	FTIR, HME, NIR, Raman, TSG	FTIR, HME, IR microscopy, NIR, NMR, Raman, TSG, UV-Vis, XRD
High-end instrumentation gives you the edge to discover your next breakthrough in a shorter timeframe	Multi-purpose equipment enables you to develop the right analytics to ensure your drug quality and performance	Reliable equipment and analyzers empower you to confidently produce your small-to-medium batches	Highly automated workflows and analyzers help you safeguard your process from incoming material through production and final product ID

- Analyze multiple components simultaneously
- Discover innovative solutions faster
- Meet quality and regulatory standards

Step 1: Research and Discovery

Basic research and feasibility study methods drive the understanding of the underlying disease mechanism, identify the therapeutic target, and enable selection of promising drug candidates for that target to advance to the next step in the process. Discovery incorporates assay development and high-throughput screening methods to further identify, analyze, and characterize the most promising small molecule and biotherapeutic compounds, assess how the candidates perform in testing *in vitro* and *in vivo* with drug, metabolism, and pharmacokinetic (DMPK) studies and then choose how to effectively formulate the drug for delivery.

The process of identifying and validating the target of interest and identifying potential lead compounds.

TSG/HME

- Produce extruded and granulated formulations

Raman

- Perform rapid, quantitative analysis at micro levels with minimal sample preparation
- Equipment with open architecture
- Streamline material analysis with OMNIC Paradigm Desktop Software

FTIR

- Streamline material analysis with OMNIC Paradigm Desktop Software
- Simplify data collection and rely on the security of database storage
- Acquire spectra from far-infrared to visible

XRD

- Identify polymorphs
- Validate crystalline structure and amorphous content
- Non-destructive analysis
- Suitable for very small quantities

UV-Vis

- Count on accurate, reliable performance
- Meet quality and 21 CFR Part 11, USP, EP compliance with Evolution 350 UV-Vis software

Micro UV

- Minimize sample handling
- Measure highly concentrated analytes
- Meet quality and 21 CFR Part 11 compliance with NanoDrop One UV-Vis software

Method/application	Spectroscopy tools
Understanding the disease mechanism	LC-MS, Raman, UV-Vis
New chemical synthesis	FTIR, MS, UV-Vis
Biomolecule analysis (proteins, peptides, nucleic acids)	Micro UV, UV-Vis, FTIR, Raman
Material characterization (physicochemical properties, secondary structure and conformation, crystallography/crystallinity, API domain, morphology)	UV-Vis, EM, XRD, SPM, Raman
Assay development	FTIR, Raman, NIR, UV-Vis
Process development	MS, NMR, NIR, HME, TSG, Raman
Crystallography	XRD
DMPK studies	Raman, UV-Vis

Step 2: Development

This step delves into pilot-scale development of the drug, addressing the analytical methods, process chemistry, process development and optimization, and approaches for scaleup. Early development also encompasses the formulation process to assess the best composition and compounding method of the active pharmaceutical ingredient (API) and other necessary components for safe, timely, and effective delivery to the therapeutic target.

The process for advancing a lead compound from discovery to clinical trial through testing (pharmacokinetics, toxicology, and more), formulation, and synthesis scaleup.

TSG

- Produce extruded and granulated formulations

HME

- Enhance solubility of API
- Create consistent dispersion of API
- Address stability, taste, dosage form, and other characteristics

NIR

- Monitor and analyze the workflow inline
- Quality control process and method development

Raman

- Assess bioavailability, molecular structure, and stereochemical conformation of formulation and corrections
- Visualize API/excipient distribution
- Streamline material analysis with OMNIC Paradigm Desktop Software

FTIR

- Analyze powders and liquids directly
- Streamline material analysis with OMNIC Paradigm Desktop Software
- Simplify data collection and rely on the security of database storage

XRD

- Identify and investigate all polymorphs
- Assess API stability with aging/temperature & humidity
- Meet GMP recommendations and 21 CFR part 11 requirements

Method/application	Spectroscopy tools
Formulation design and optimization (proportion of ingredients, polymer composition)	XRD, FTIR, HME, Raman, TSG
Drug delivery systems (injectable implant, tablet, powder, softgel, nanoparticle, orally disintegrating films, patches, other) and dosage forms (solid oral, transdermal, transmucosal, subcutaneous, buccal)	FTIR, HME, TSG
Coating analysis	Raman, FTIR microscopy, NIR
Solubility enhancement	HME
Timed delivery enhancement (controlled, extended, sustained, delayed release)	HME, TSG
Compounding	HME, FTIR
Extrusion (coextrusion, hot melt extrusion)	HME
Granulation (twin-screw, wet, dry, continuous))	TSG
Continuous manufacturing	NIR, Raman, HME, TSG
Dispersion analysis (amorphous solid dispersion, crystalline solid dispersion)	XRD
Stability testing	Raman, XRD
Raw material testing	FTIR, XRD
API distribution	Raman
Polymorphism analysis	XRD, Raman

Step 3: Clinical Study

This step covers the typical Phase I, Phase II, and Phase III clinical trial aspects with human participant groups in increasing scale. While our instrument portfolio is typically designed for research use and not mapped to methods or applications for use with human samples, certain instruments can be helpful to adjust the upcoming manufacturing process to enhance solubility and bioavailability of the API (HME) or to manage implementation of continuous manufacturing (TSG).

The process of doing experiment or observations done in clinical research to generate data on safety and efficacy.

TSG

- Produce extruded and granulated formulations
- Implement continuous manufacturing
- Reduce human error and enhance productivity

Raman

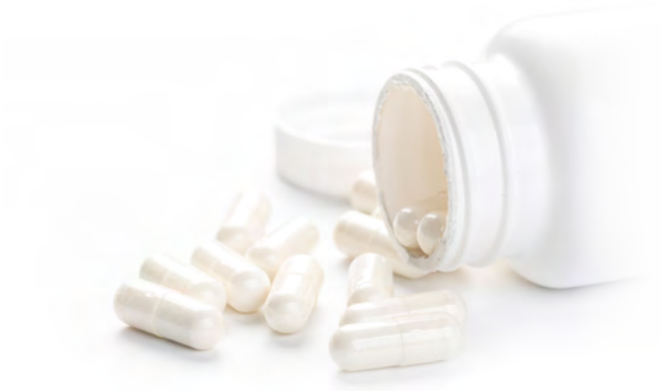
- Profile drugs in living cells
- Expect stable performance with minimal downtime
- Couple and customize to almost any equipment with open architecture

FTIR

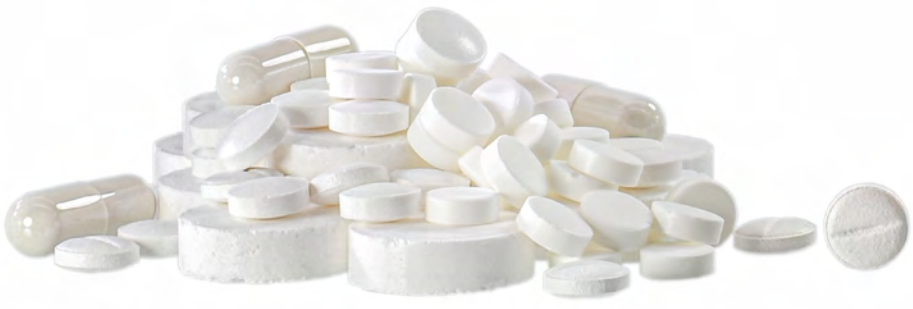
- Simplified data collection
- Achieve high-quality results on small samples
- Can acquire spectra from far-infrared to visible

HME

- Enhance solubility of API
- Process scale-up



Method/application	Scope
Phase I – safety, tolerability, pharmacokinetic (PK) studies	Assess safety in a small population of healthy humans
Phase II – dose range finding, early side effects, GMP formulation	Assess therapeutic effects in midsized population of healthy and diseased humans
Phase III – large-scale safety, efficacy studies	Assess long-term effects in larger population of humans.



Step 4: Manufacturing

This step addresses the process scale-up that occurs in industrial-scale manufacturing, as well as the associated tasks involved with surrounding procedure and production.

Industrial-scale production of pharmaceutical drugs: hot-melt extrusion, milling, tablet pressing, coating, etc.

TSG

- Produce extruded and granulated formulations

NIR

- PAT
- QA/QC
- Monitor and analyze component mixing inline
- Test finished products
- Meet quality and 21 CFR Part 11 compliance with ValPro package and OMNIC Security Suite software

Raman

- Test finished products
- QA/QC
- Reduce operator variability
- Meet quality and 21 CFR Part 11 compliance with ValPro package and OMNIC Security Suite software

FTIR

- Test finished products
- QA/QC
- Analyze packaging material
- Simplify data collection and rely on the security of database storage
- Meet quality and 21 CFR Part 11 compliance with ValPro package and OMNIC Security Suite software

XRD

- Test finished products
- QA/QC
- Identify polymorphs
- Take transmission and reflection measurements in the same configuration
- Meet quality and 21 CFR Part 11 compliance with ARL EQUINOX XRD system software

UV-Vis

- Assess sample quantity and purity
- Meet quality and 21 CFR Part 11, USP, EP compliance with Evolution 350 UV-Vis software

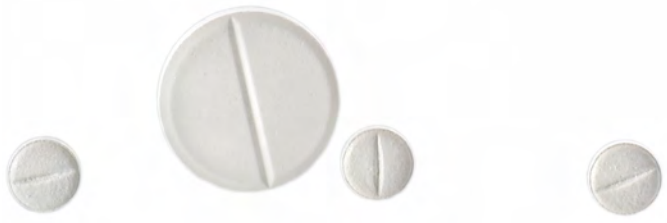
HME

- Process scale-up
- Create new dosage forms and delivery systems

IR Microscopy

- Analyze final packaging material

Method/application	Spectroscopy tools
Quality checks (raw materials, finished goods, performance qualification consultation, batch and lot analysis, QA/QC)	FTIR, XRD, NIR, UV-Vis, Raman
Process control (reaction monitoring, bioreactor monitoring, feedback/feed-forward/real-time monitoring, fluid bed drying/moisture/residual solvent analysis)	FTIR, NMR, NIR, XRD
Regulatory compliance (USP/PHEUR, FDA, data security, informatics, traceability, auditing trails, analytical instrument maintenance, calibration, and certification, IQ/OQ/PQ qualification consultation)	OMNIC security suite software and ValPro Package
Solubility enhancement of API	HME with Raman
Continuous manufacturing	TSG
Inline analysis of component mixing	NIR
Packaging material analysis	IR microscopy, Raman microscopy



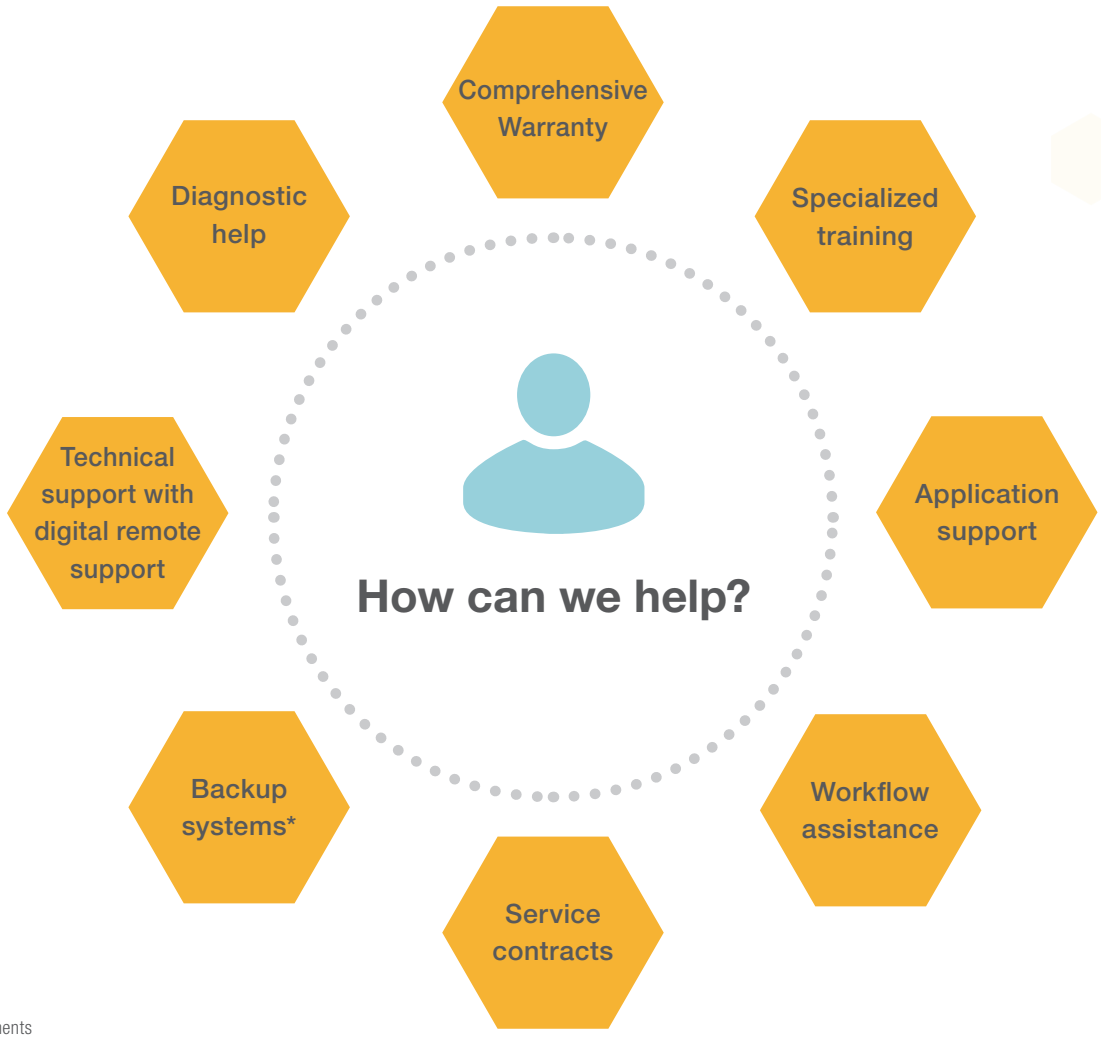
Overarching quality from start to finish

Quality control and assurances throughout the pharma process include practices to help identify potential drug contaminants, ensure product safety and consistency, and maintain regulatory compliance. Our instruments not only formulate the drugs, but also help analyze and record data from inbound and raw materials through outbound and finished goods across the entire workflow. Our team can provide the exceptional service and support critical to ensure minimal downtime throughout the process and whenever you're ready to release a batch or crucial product.

Our instruments and services that analyze, qualify, and manage product quality help assure that you can deliver safe, world-class solutions

Application	Before you begin	Research and discovery	Development	Clinical study	Manufacturing
Inbound and raw material analysis		●	●		●
Outbound and finished goods analysis		●	●		●
Data integrity		●	●	●	●
Traceability		●	●	●	●
Minimize sample handling			●		●
Sample purity/ contamination		●	●	●	●
Minimize downtime		●	●	●	●
Stable performance		●	●	●	●
Service and support	●	●	●	●	●

Surrounded by support



* Excluding XRD instruments

Thermo Fisher Scientific understands the importance of instrument uptime in pharmaceutical QA/QC labs. This is why we offer a broad range of service offerings to ensure timely response and repair of mission-critical instruments. We offer comprehensive, worldwide after-sales service and support, including instrument installation, on-site technical consultancy, applications support, instrument qualification, and compliance services. Our customers may also take advantage of our Premier offering, which includes a two-day on-site response or industry-exclusive no-charge requalification guarantee if you add OQ to a qualifying plan—imagine hassle-free help with audit-readiness for your GMP compliance. Our global team of expert consultants can also help you understand 21 CFR Part 11 and pharmacopeia requirements as you navigate complex industry requisites.

Our teams of experts are at customer sites every day

Service

Draw on our deep expertise to unleash the potential of your discovery. With our global business infrastructure and experienced key account management team, we can provide exceptional post-sale support to follow instrument installation—by certified engineers who are ready to respond to your requests for calibration service, routine maintenance, corrective maintenance repairs, emergency response, and other warranty and post warranty service contracts. And if you need more help, we have instructors who have developed and used the product, developed the applications and methods, and maintained the instruments to help you train your team.

- Wide range of service offerings
- Compliance solutions for regulatory management
- On-site service and scientific support
- Application support
- Asset and supply management

>2,000
service specialists globally

18 years
average FSE experience

Learn more about how to ensure your uptime with our service and support:

Unity Lab Services for FTIR, NIR, Raman, UV-Vis, and micro UV-Vis

- Contact technical support
- Instrument service advantages
- Service Plan Options
- Top 3 reasons to consider service beyond a factory warranty
- Digital Remote Support keeps labs running smoothly

Services for spectroscopy, extruders and rheometers (material characterization) and X-ray diffraction products (XRD)

- Contact technical support
- Learn how pharmaceutical extrusion can help you realize better drugs and novel drug delivery systems
- OES, XRF and XRD service solutions
- Rheometers & viscometers

Resource centers

- At-line and in-process monitoring in pharmaceutical manufacturing
- Discovery to QC resource center
- Drug formulation and manufacturing resource page
- UV-Vis Testing Solutions for Pharmaceuticals
- Micro UV-Vis resource: Intelligent microvolume analysis
- UV-Vis resource: Precision performance for advanced analysis
- Nicolet Summit integrated computer
- Security and compliance resource: Nicolet Summit FTIR Spectrometer and OMNIC Paradigm Software

Learning centers

- Spectroscopy, elemental & isotope analysis learning center
- MC pharmaceutical extrusion learning center

Service resources

- Lab instruments & equipment services
- Compliance and calibration services
- Service packages for rheometers, viscometers, mixers and extruders
- Patheon: Thermo Fisher Scientific provides industry leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand

Library

- A case study of using FT-NIR for pharmaceutical melt extrusion process monitoring
- Confocal Raman analysis of a transdermal nicotine patch by a DXR2 Raman Microscope
- Dynamic structural studies of pharmaceutical products using ARL EQUINOX Series X-ray diffractometers
- Ensuring safer and effective pharmaceutical formulations by X-ray diffraction
- Evaluating Active Ingredients in Pharmaceutical Hot Melt Extrusion Products with Raman Imaging
- FT-Raman mapping of multicomponent solid dosage forms
- Guide to pharmaceutical standards for Thermo Scientific UV-Vis Spectrophotometers
- Innovative rheological and extrusion solutions for drug development
- Thermo Scientific Pharma *mini* Implant Line: The complete solution for injectable drug delivery systems
- Validated systems for pharmaceutical environments (Evolution UV-Vis spectrophotometers)
- XRD Investigation of Ibuprofen with ARL EQUINOX 100 in Transmission Mode

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