



PHARMA

Fourier 80 Benchtop NMR for Pharmaceutical Quality Control

Increase Confidence. Limit Risks. Streamline Life Cycle Management.

Innovation with Integrity

Streamlined Quality Control

Leverage the Unique Features of NMR for Modern Procedures.

The Fourier 80 follows the **universal** NMR principles, which facilitates the life cycle management of the instrument and procedures.

- Simplify system qualifications and monitoring
- Accelerate method validation
- Offer straightforward risk-assessment
- Enable platform procedures



The Fourier 80 is inherently **quantitative** by nature, allowing the development of analytical procedures that:

- Are bias-free
- Allow direct uncertainty analysis
- Do not require identical reference standards
- Simplify investigations



Based on one of the most **robust** analytical technologies, the Fourier 80:

- Streamlines method transfer
- Limits the risk of false Out Of Specification results
- Offers very large Method Operable Design Regions
- Provides maximal flexibility and confidence



Tailored for Analytical Quality by Design

The incentive for improved risk-analysis, deeper understanding of analytical procedures, and enhanced variable identification is growing, following the recent revision of ICH Q2, and the introduction of ICH Q14. Based on well-established physical principles, NMR uniquely stands out to meet the needs of Analytical Quality by Design. The inherent quantitative nature and predictive variable control makes the entire life cycle of NMR procedures simpler than other technologies. By enabling platform procedures, NMR provides a unique combination of flexibility and robustness to build quality into every analytical procedure.

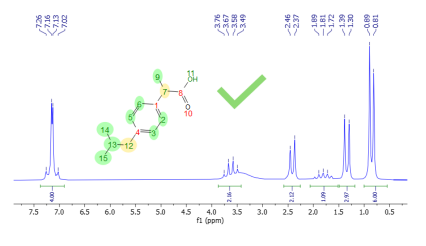


Analytical Toolbox for Quality Control

No Identical Standard. No Calibration. No Contact.
Maximal Efficiency.

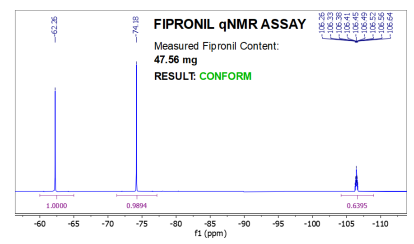
The Ideal Tool for Robust and Efficient Identification Testing

The universality and specificity of NMR enable robust identification testing with the Fourier 80, eliminating the need for reference standard management. NMR quantitative fingerprints enable specific, numerical acceptance criteria, preventing subjective assessments and enhancing confidence. With contactless procedures and no instrument preparation, NMR prevents the risk of cross-contamination and accelerates quality control testing.



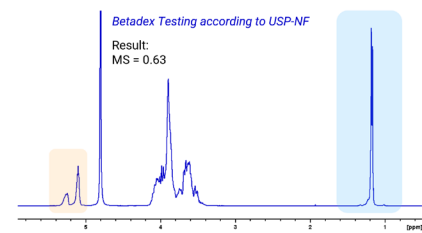
Quantitative Assays Made Simple

From raw material to finished product, the Fourier 80 enables simple quantitative assay design in a few steps. NMR does not require identical reference standards, allowing the use of any surrogate compound, simplifying standard management. With its quantitative nature, NMR eliminates the need for calibrations and complex analytical sequences, providing absolute quantitative values in a single measurement.



Straightforward, Cost-Efficient Compendial Testing

While only a few dozen monographs of the compendium currently require NMR testing, some involve testing of critical excipients, such as poloxamers and betadex. The Fourier 80 allows simple implementation of these tests (directly or as alternative procedures) for cost-efficient operations.



Reduce Investigation Efforts and Save Time

NMR is the most powerful analytical tool for structural characterization. With a unique set of orthogonal experiments, the Fourier 80 can qualitatively and quantitatively probe a sample to easily investigate Out Of Specification results and elucidate unknown species. Additionally, these investigations can be carried out on the same system as for routine testing or easily transferred between systems, regardless of the field strength.



Built-in GMP Support for Compliance

Peace of Mind. Hassle-Free. State-of-the-Art.

Built on years of expertise, Bruker's GMP solution ensures hassle-free and streamlined compliance. The **Bruker GxP kits** contain the necessary components and features to fully integrate the Fourier 80 in a regulated environment. This supports laboratories in achieving full GMP compliance, data integrity and conforming to the 21 CFR Part 11 and Annex 11 of EU-GMP requirements.

- Electronic signatures
- Full audit trail capabilities
- IQ/OQ protocols
- State-of-the-art user management
- GxP qualified engineers

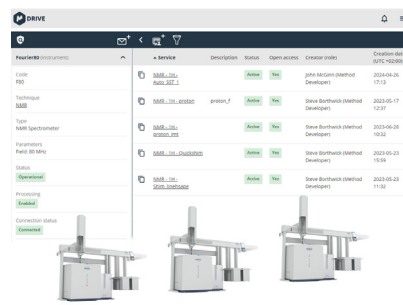
Flexible Solutions for all Laboratory Topologies

Bruker solutions are adaptable to any laboratory requirement and organization without compromising compliance.



The **GxP Readiness Kit for Fourier** is ideally tailored for small-sized laboratories or for a single NMR facility. This kit provides all the tools to **achieve compliance** as a standalone installation at a competitive price. The system is managed directly on the workstation and data is secured on-premise. A dedicated, simplified user interface (GoScan) allows non-expert operators to submit their samples in just a few steps.

The **GxP Readiness Enterprise Kit for Fourier** is perfect for laboratories with multiple NMR systems or a distributed topology. The client/server architecture supports multiple spectrometer connections and administrations across an organization. Operators submit samples and reviewers access data from any authorized via a secure, user-friendly web-based interface (Mdrive). The internal database assures the **highest degree of data integrity** while remaining easy, efficient, and globally accessible.



Solutions for Full Automation

Quality control analytical procedures require full automation to eliminate potential bias from manual processing, ensure efficiency, and minimize operator training. Fully automated, compliant NMR routine QC testing with the Fourier 80 is achieved using its autosampler, which which holds up to 120 samples. Combined with the industry-leading Bruker software (Topspin, ICON-NMR, GoScan, Mnova) and supported by Bruker GxP kits, it ensures maximal confidence, efficiency, and sample throughput.



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Solutions for QC



Solutions for Pharma

