High-Resolution NMR Testing for Pharmaceuticals

Health Inspired, Quality Driven.

SGS

We are proud to introduce high-resolution nuclear magnetic resonance (NMR) testing to our good manufacturing practice (GMP)-compliant analytical testing portfolio in China, expanding our capabilities in structural elucidation, impurity profiling and quantitative analysis for the pharmaceutical industry.

A new benchmark in GMP structural testing

Throughout the drug development and manufacturing process, GMP compliance is essential to guarantee product safety, efficacy and quality. NMR provides a non-destructive, information-rich tool to support these objectives, delivering highly detailed molecular insights that complement conventional chromatographic and spectroscopic techniques.

JEOL 400 MHz NMR – precision meets compliance

The JEOL 400 MHz superconducting NMR spectrometer combines high sensitivity and resolution with full 2D capabilities – heteronuclear single quantum coherence (HSQC), heteronuclear multiple bond correlation (HMBC) and correlation spectroscopy (COSY).

Equipped with a GxP Readiness Kit, it supports good laboratory practice (GLP)/GMP qualification and validation activities – installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) – ensuring compliance for both qualitative structural characterization and quantitative analysis.

Applications under GMP

- Active pharmaceutical ingredient (API) structure confirmation – complete elucidation of molecular framework and stereochemistry for batch release
- Impurity and degradation identification – detects trace impurities at ≤0.1 % w/w without chromatographic separation
- Polymorphism analysis – differentiates API crystal forms non-destructively, supporting form control during production
- Quantitative NMR (qNMR) – provides SI-traceable purity and assay results with exceptional reproducibility

Quantitative power and efficiency

Using internal standard methods, the qNMR approach enables direct, calibration-free quantitation.

Benchmark testing using the JEOL 400 MHz system has demonstrated:

- API assay precision (relative standard deviation (RSD) of 0.28%), comparable to high-performance liquid chromatography (HPLC) (0.35%)
- 70% reduction in sample preparation time
- Detection of fluorine impurities (^{19}F qNMR) down to 0.05 % w/w, consistent with ICH Q3B guidelines

GMP validation and data integrity

All analyses are performed on a fully validated computerised system (IQ/OQ/PQ) with robust data integrity procedures.

We support operator qualification, routine revalidation and full lifecycle maintenance in alignment with regulatory expectations.

Now available in China, this cost-effective, high-throughput service is ideally suited for routine quality control, identity testing, purity assessment and quantitation of synthesized drugs and raw materials.

With the launch of GMP-compliant NMR testing, clients benefit from enhanced analytical confidence and fully traceable results – helping ensure every drug product meets its promise.

High-Resolution NMR Testing for Pharmaceuticals

Health Inspired, Quality Driven.

Contact us

pharma.cn@sgs.com

sgs.com/pharma

SGS

When you need to be sure