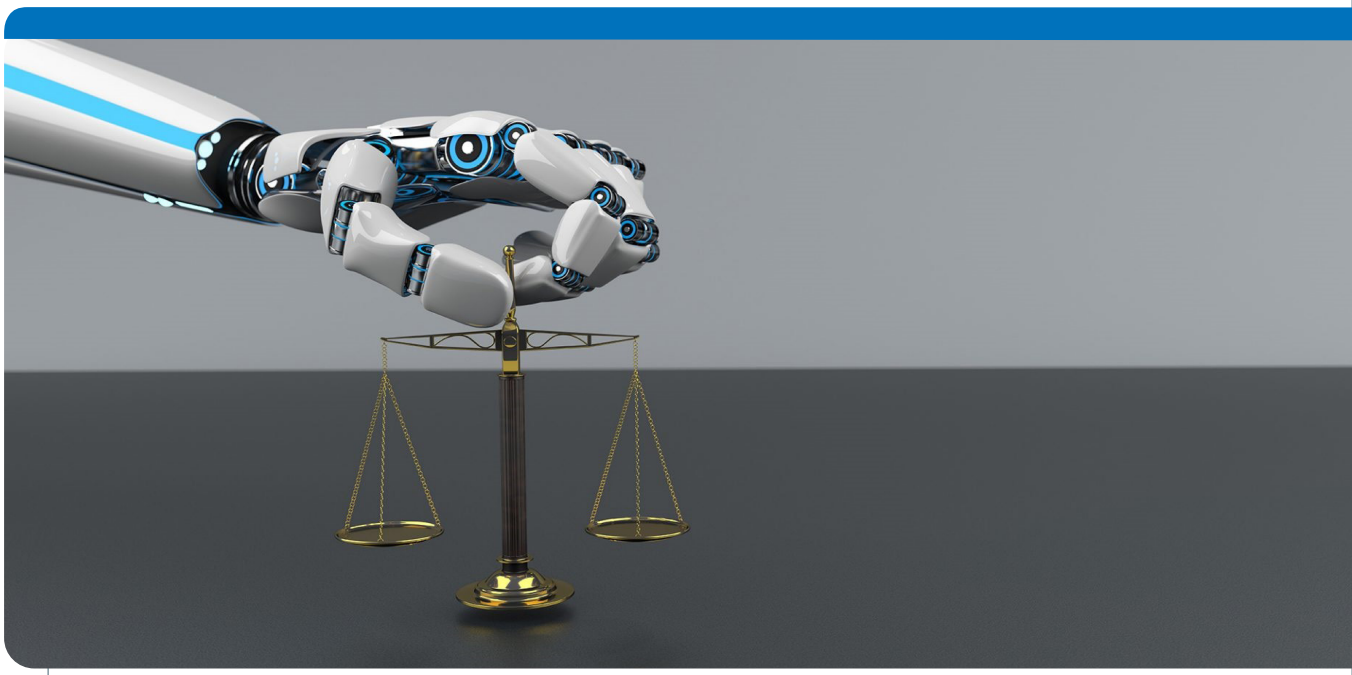


Potency Determination

- Accelerating purity assays with Mdrive qNMR, also under GxP

Potency calculation, purity assessment, identity testing, residual solvent, moisture analysis, relative response factor calculation…. Have you thought about using quantitative NMR (qNMR) as a one-stop solution?

Potency determination by qNMR has been shown to be a single point replacement for routine development testing which previously involved several experiments and techniques.[1] The downside is that existing workflows rely on expert knowledge and/or well-trained analysts and detailed protocols.

Building on the Mdrive platform, Mdrive qNMR streamlines potency determination. An automatic workflow from sample submission to final report, makes it the ideal solution for both experts and non-experts working in a pharmaceutical development environment, where quality is a must.

[1] Webster G.F. and Shailendra K., Anal Chem, 86, 11474 (2014)

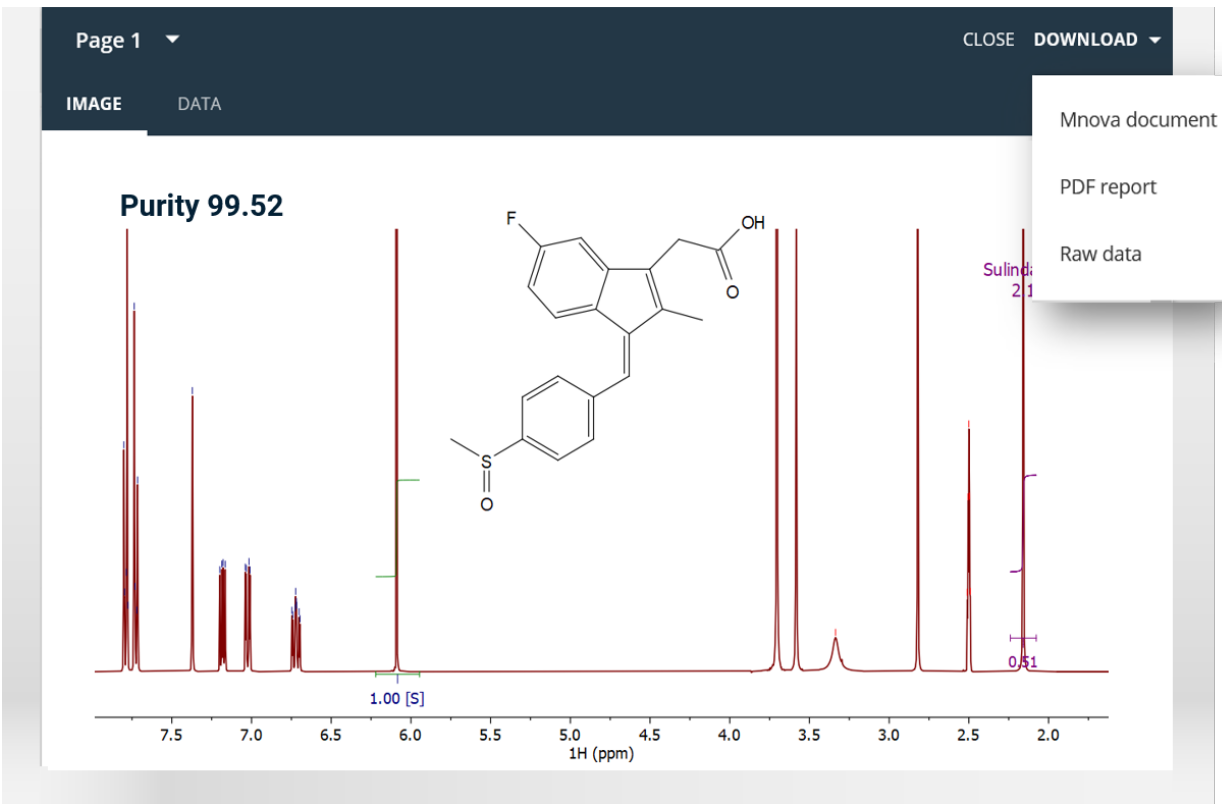
Your Benefits

- **Versatile:** No need for a chemically identical reference material. Commercially available reference standards are used.
- **Faster:** NMR is inherently quantitative. There is no need to calculate response factors or calibration curves.
- **All-in-one:** Potency and structure confirmation in one single experiment. Organic and inorganic materials are taken into account. No need to use additional techniques.
- **Accurate:** Use of internal standard eliminates errors introduced by inherent sample differences.
- **Reproducible:** An automated workflow from acquisition to reporting decreases human error and variability.
- **Intuitive and flexible:** Straightforward manual interaction when desired.

Key Features

- Web-based sample and analysis management.
- Automated data analysis comprises potency calculation, using values obtained by integrating either automatically selected or predefined spectral regions.
- Wide range of integration methods, including Global Spectra Deconvolution (GSD) and quantitative GSD (qGSD).
- Results are delivered in electronic format and as PDFs, with customisable templates.
- Rapid qNMR method development based on optimized default, but configurable, parameter sets for acquisition, processing and analysis.
- **Data integrity** and **21 CFR part 11** compliance.[2]
- Approval workflow and electronic signatures.[2]
- Audit trail from the beginning to the end of the workflow, including the method development stage.[2]
- Data is automatically stored in a database.[2]

[2] Refer to 'GxP Readiness Kit – New Generation' brochure for more detailed description of GxP and laboratory management features and benefits.



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