Potency Determination

Streamlined Workflow

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 qNMR workflows rely on expert knowledge and/or well trained analysts and detailed protocols.

Bruker's new potency determination tools streamline this process with a fully automatic workflow from sample submission to report, making 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 Kumar S., Anal Chem, 86, 11474 (2014)

Potency by NMR - Your Benefits

- Versatile: no need to have a fully characterized reference standard for the analyte. 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 analysis decreases human error and variability
- Intuitive and flexible: straightforward manual interaction when desired

Key Features

- Straightforward sample submission through IconNMR automation software
- Optimal qNMR experiments provided as well as parameters for most commonly used internal standards
- Automated data analysis comprises internal standard peak identification and integration with sophisticated 'peak snapping' algorithm, analyte quantification, consistency analysis and potency calculation
- Error analysis within the sample: multiple analyte peaks are integrated, averaged and the RSD given
- Error analysis between samples: replicate samples can be submitted. Potency for each replicate will be calculated. Final averaged result and associate error given
- Results are presented in different formats such as PDF report with spectral information and excel table output

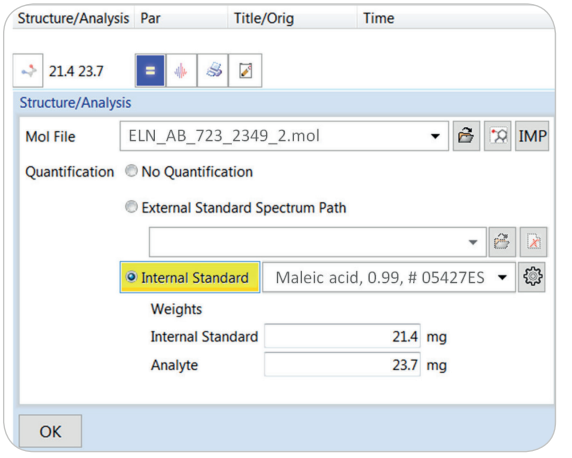
The automatic data analysis is based on Bruker's proven algorithms for NMR quantification. These are either automatically called from the acquisition module or they can be manually executed. In addition to the automatic analysis, all processing features and the subsequent analysis are accessible for manual work in an easy-to-use fashion.

Sample Preparation

Weighing of analyte and internal standard, dissolution and transfer to the NMR tube

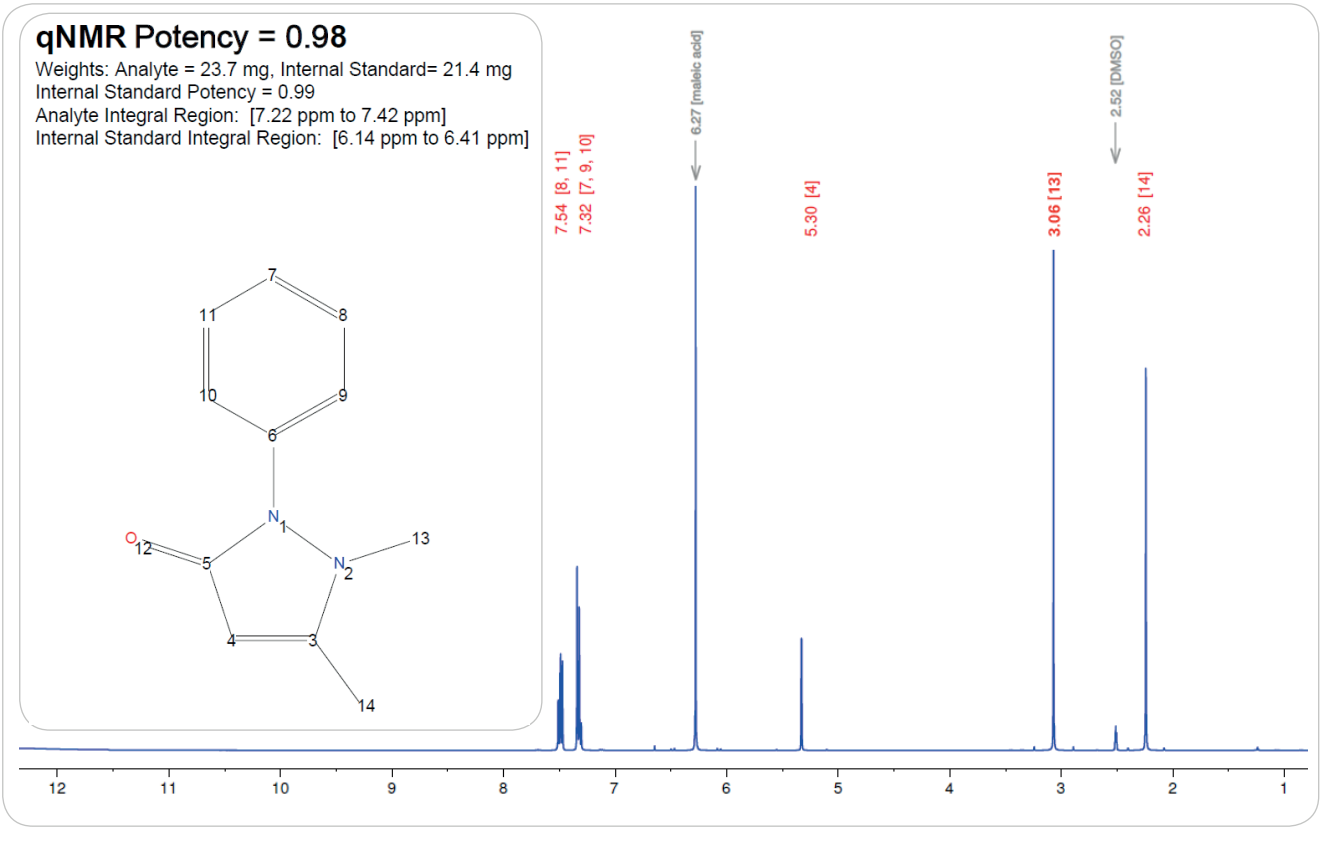
Sample Submission

Experiment and internal standard selection, weights input



Results

Spectra, potency, Excel table and PDF Report



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