

Kansas Analytical Services LLC

Your Leading Source for Pharmaceutical Solid-State NMR Analysis

Solid State Nuclear Magnetic Resonance (SSNMR) spectroscopy is a powerful, nondestructive analytical tool for the characterization of pharmaceuticals. KAS offers its clients a wide range of benefits including:

Experience

KAS has completed more than 200 projects for more than 80 clients ranging from small biopharma's to Fortune 50 companies.

For our clients, this means that we have the ability to perform virtually any experiment required on any nuclei of interest.

Expertise and Focus

KAS serves exclusively the pharmaceutical community. Our founding partner and senior consulting analyst, Professor Eric Munson, Professor in the Department of Industrial and Physical Pharmacy at Purdue University, is a recognized expert in pharmaceutical chemistry and SSNMR applications with more than 100 peer-reviewed publications. Dr. Matthew Nethercott, senior analyst, is an expert in solid-state NMR analysis of pharmaceuticals. Dr. Michael Hanrahan, analyst, has expertise in a broad range of solid-state NMR methods.

For our clients, this means that we can provide the highest quality experimental design, data analysis, and interpretation.

State-of-the-Art Experimental Capability

KAS operates two Bruker AvanceNEO spectrometers. The NEO is Bruker's latest product offering and provides a wide range of new features including multi – channel transmit and receive capability, a range of options for system operation and data analysis, and compatibility with Topspin 4, Bruker's newest NMR software which is GxP ready.

For our clients, this means access to state-of-the-art experimental capability and improved reliability and redundancy.

REF-GEN-001

Implementation of Good Manufacturing Practices

KAS has completed the implementation of Good Manufacturing Practices (GMP) at the laboratory and the NEO systems. Bruker utilizes a new version of Topspin 4 which is designed to support compliance with 21 CFR Part 11. This software provides complete capability for the implementation of data integrity (DI) practices including audit trails, data set locking, electronic signatures, and other features. Lillian Lynn, an experienced medical quality professional, serves as Director of Quality. We have successfully completed several GMP audits with major pharmaceutical companies.

For our clients, this means the opportunity to perform analyses requiring GMP compliance including NDAs, lot release, and post-marketing surveillance.

Responsiveness and Cost-Effectiveness

Our two 400 MHz NMR spectrometers are robust platforms that provide high signal- tonoise for rapid data acquisition. Typical turnaround time for analysis projects, depending on the number of samples required, is two to four weeks. We can also provide very attractive pricing for multiple sample quantities.

For our clients, this means rapid, economical project completion.

Protocols for Analysis of Highly Potent Compounds and Controlled Substances

KAS has developed and validated a protocol for safely analyzing highly potent compounds including Band 4 and Band 5 materials. KAS also holds a DEA license for the analysis of Schedule 2-5 controlled substances.

For our clients, this means the opportunity to use the power of solid- state NMR to characterize compounds that are impossible to analyze in-house.

We look forward to assisting you with your solid-state NMR analytical requirements. Please contact us at <u>inquiry@kansas-analytical.com</u> or contact

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