KCAS
Bioanalytical & Biomarker Services

Led by strong, recognized pharmaceutical and biopharmaceutical experts and pioneers in bioanalytical and biomarker services, KCAS has proven success with over 40 years of stable, secure growth.

KCAS
10830 S Clay Blair Blvd
Olathe, KS 66061 USA
(913) 248-3000
www.kcasbio.com

Dose Formulation Analysis at KCAS

Dose Formulation Analysis is an essential step in regulated nonclinical studies. Robust analytical methods, rapid turnaround, and efficient communication helps ensure the dose form results for your GLP studies are delivered on time.

At KCAS, our scientific expertise allows us to develop methods that achieve your study requirements. Our experts understand the different complexities involved in dose formulation vehicles as well as complex biological matrices. This means we develop validated methods quickly, using the appropriate analytical tools for your studies.

KCAS delivers high quality data on time to our customers, helping them in their drug development needs.

KCAS has significant experience in all aspects of dose formulation analysis. Methods utilizing either UV/Vis or Fluorescence detectors, whichever is appropriate for your protein or small molecule. In addition, KCAS has substantial infrastructure and decades of expertise in qualitative and quantitative separations utilizing HPLC mass spectrometry detection of peptide drugs. Solid, semisolid, and liquid formulations of pharmaceutical leads are one key step in drug development.

Methods are optimized to confirm the API mg. vs g. concentration in your dosing formulation, as well as solution uniformity, and stability. In addition, if stereoisomers are part of the formulation, we have years of chiral experience at your service.

KCAS Bioanalytical & Biomarker Services
FlowMetric a KCAS company
ACTIVE BIOMARKERS A KCAS COMPANY

Visit kcasbio.com for more info

Key KCAS DFA Differentiators

- Fast method transfer, development, and GLP validation (< 20 days)
- Competitive pricing for any budget
- Method assessments for proof of concept
- GLP formulation stability covering all your dose form studies
- Professional eCTD FDA ready GLP study reports
- Homogeneity, compatibility, and in-use stability studies
- Single-contact project management and IND guidance
- Certificate of testing preclinical analysis for test and control articles
- State of the art 70,0000 sq ft analytical laboratory
- Method Development with limited API during CMC stage
- GLP analysis of dose form suspensions, solutions, capsules, or feed
- Quantitative analysis of challenging formulations using RP-UHPLC-UV, SEC-HPLC-UV, LC-MS/MS, NanoDrop
- Expertise with difficult formulations of proteins, peptides, biologics, and polymers

Technical Capabilities

Following GLP FDA 21CFR58 OECD, KCAS develops and validates our Dose Form Testing Methods (UHPLC-UV, UHPLC-FLD, or LC-MS/MS) for precision, accuracy, linearity, range, specificity, and limit of quantitation. We follow dose formulation validation guidelines from AAPS. After method development and validation of test methods for each vehicle, we perform GLP formulation stability studies in parallel with Dose Formulation Studies. Formulation Stability Studies cover each Test Method across all Dose Form Studies. We assess the longest storage time across studies and all formulation storage/shipping temperatures using the lowest and highest study formulation concentrations. Depending on the high dosing concentrations, we may need up to 1 g of test material to perform the Stability Studies for each test method at usually 3-time points.