CANNABINOID EXPERTISE





Count on Reliable Cannabinoid Bioanalysis

ABS Laboratories, part of ACM Global Laboratories, specializes in complex assay method development and validation for the quantification of drugs, metabolites, and biomarkers in biological samples for preclinical and clinical trials from research to final regulatory submission.

As a class of compounds, the cannabinoids have vast therapeutic potential, which has led to extensive scientific investigation. For over a decade, our lab has used validated LC-MS/MS and GC-MS assay techniques to determine the bioavailability of various cannabinoids, and their metabolites, from a variety of different formulations and routes of administration.

ABS Laboratories facilitates studies designed to investigate potential clinical applications of cannabinoids for the treatment of various diseases and health conditions such as oncology, metabolic diseases, pain, addiction, epilepsy, multiple sclerosis, and other therapeutic areas.

Complex Assay Development

Our expertise helps expedite development of any custom cannabinoid assay, some that may involve quantifying up to 7 different analytes in a single plasma sample. The list that follows outlines basic information about our key bioanalytical assays.

Non-proprietary Assays

CBD, THC & 11-OH THC in plasma and a variety of other matrices to support regulatory preclinical & clinical studies since 2000.

- Initial assays used GC-MS
- Present assays use LC-MS/MS
- Variety of validated calibration ranges dependent on study requirements.
- Current human plasma LC-MS/MS assay uses our AB Sciex 6500 and has a lower limit of quantification of 0.05 ng/mL

Total 11-COOH THC in human urine

• 1 to 500 ng/mL

Endocannabinoids in human plasma

- Anandamide (AEA) 1 to 5 ng/mL
- 2-arachidonoylglycerol (2-AG) Stabilization required as 2-AG is prone to spontaneous isomerization to 1-AG 1 to 50 ng/mL

Put Our Experience to Work for Your Next Cannabinoid or Endocannabinoid Research Study

Our company has significant experience in supporting pharmaceutical companies, academic institutions, and government agencies in the US, UK, and other countries around the world. ABS offers fully validated GLP assays in a range of matrices and models for CBD, THC and its metabolites, 11-hydroxy THC, and THCV. We also develop bespoke assays for other cannabinoids as needed and use validated assays to profile the pharmacokinetics (PK) of cannabinoids whether the administered drug is synthetic or a medicinal extract.

Case Study - Company X

Support up to Regulatory Submission for EMA & FDA Submission

Below are examples of our company's support of a valued customer up to regulatory submission to the EMA and FDA. This demonstrates our contribution to the rapidly growing field of cannabinoid research.

	Studies	Specific Support Provided	Additional Information
Sativex	Multiple Preclinical	Assays for the analysis of CBD, THC, and its active metabolite, 11-hydroxy delta-9-tetrahydrocannabinol (11-OH- THC) in plasma and a variety of tissues	Supported a variety of preclinical studies in rat, dog, and rabbit; also looked at levels in tissues (brain, liver, sciatic nerve) and milk
	Phase 1 Study	Plasma samples were collected at designated time points for analysis of CBD, THC, and its active metabolite 11-hydroxy delta-9-tetrahydrocannabinol (11-OH-THC)	Study to Assess Food Effect on Sativex Bioavalability EurJClinPharmacol(2013) 69:825-834 C.G. Stottetal <u>A phase 1 study to assess the effect</u> of food on the single dose bioavailability of the THC/CBD oromucosal spray
	Multiple Phase 1, 2, and 3 studies	Analysis of CBD, THC, and its active metabolite 11-hydroxy delta-9- tetrahydrocannabinol (11-OH-THC)	Multiple Phase 1 studies looking at the bioavailability of various formulations of CBD and THC Multiple Phase 2 & 3 studies looking at the efficacy of a variety of formulations of CBD and THC for multiple sclerosis and cancer pain
Compound X	Multiple Phase 1, 2, and 3 studies	Full Central Laboratory Services including kits, logistics, and full-safety analysis and additional specialist testing	More than 10 protocols/studies supported by ACM Global Central Laboratories First FDA approved plant-derived cannabinoid medicine

Experience Matters

Rely on the expertise of our analytical chemists to help you successfully complete your next cannabinoid clinical trial program. Contact our team today to get started.

Contact Our Team Today: acmgloballab.com/ABS