XENOTECH
A BioIVT Company

Accurate Mass Spectrometry Metabolite Profiling & Characterization

Our compound-driven, high-resolution mass spectrometry characterization studies provide critical information about the metabolism of your compound.

In light of the FDA's 2008 Guidance for Industry on Safety Testing of Drug Metabolites, *in vitro* metabolite characterization studies have assumed greater importance in the drug development process. Metabolic profiling across species can reveal important differences in the metabolism of drug candidates between humans and nonclinical species. Current regulatory recommendations highlight the need for additional toxicology studies of human-specific and disproportionate metabolites. XenoTech's accurate mass spectrometry metabolite characterization services, combined with our extensive portfolio of cellular and subcellular reagents from human and nonclinical species, offer clients a rapid and cost-effective route to early metabolite identification and selection of appropriate species for nonclinical safety assessment. Production of identified metabolites as well as characterization of samples from *in vivo* studies and synthesis of radiolabeled drug candidates are also available upon request.

Metabolite Characterization

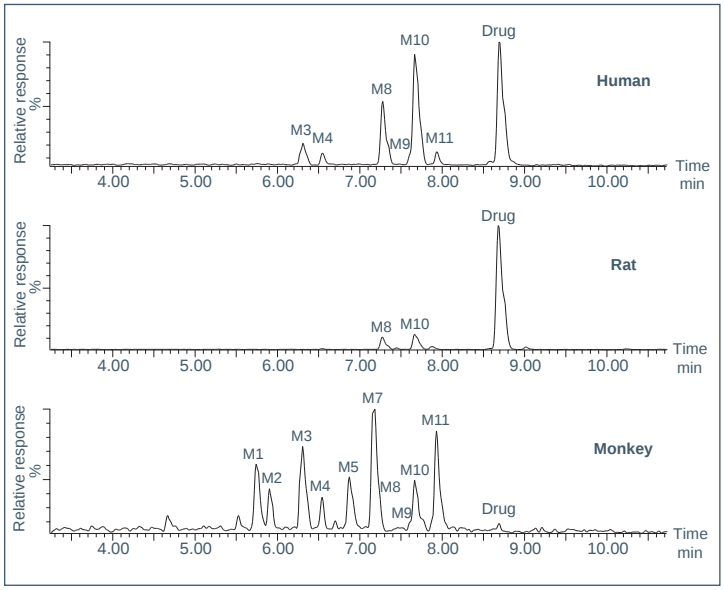
Our compound-driven studies of metabolite characterization by high-resolution accurate mass spectrometry provide extensive critical information about the metabolism of your compound in as little as three weeks. We routinely provide analyte-specific method development services, but we can also adapt your existing in-house analytical method to support our metabolite characterization studies. Using state-of-the-art instrumentation and software, our experienced analytical scientists can perform thorough metabolic profiling across multiple species and provide comprehensive metabolite structural elucidation. Our SOPs meet or exceed FDA guidance document recommendations and we incorporate rigorous checks and controls to ensure confidence in the data we generate.

A complete data summary, including proposed metabolite structures and representative chromatograms and spectra (as available), is provided upon study completion. Optionally, a comprehensive report is available for an additional fee.

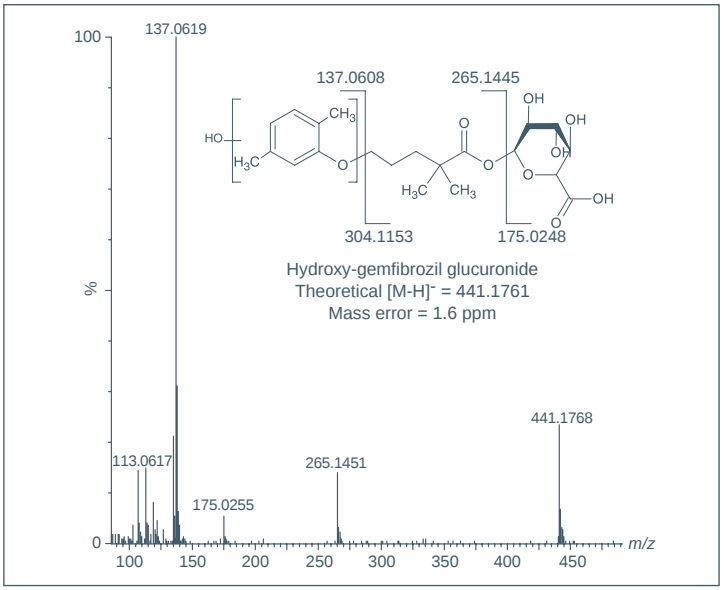
Instrumentation used for characterization:

- Waters SYNAPT™ high-definition mass spectrometry system (with IMS capabilities)
- Waters ACQUITY UPLC™
- Waters MassLynx™ and MetaboLynx™ software packages
- UV, fluorescence and radiometric detection in conjunction with mass spectrometry

  Applied Biosystems API 4000 QTrap LC/MS/MS also availabilable in-house



Mass chromatograms showing marked species differences for a drug incubated with rat, monkey or human liver microsomes



Accurate mass UPLC/MS/MS spectrum of a hydroxylated metabolite of gemfibrozil glucuronide. Hydroxylation by CYP2C8 occurs on the dimethylphenoxy moiety, as indicated

Contact us to learn more at **www.xenotech.com** or call **913.438.7450**

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