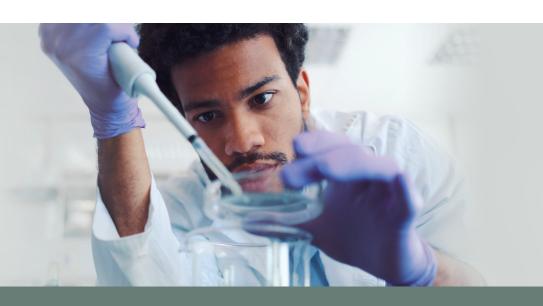


Problem Solving
Scientific Expertise
Innovative Approach



Development of an LC-MS/MS Peptide Method

NEED

- The client had attempted to conduct a peptide bioequivalence study for using standard Enzyme-linked immunosorbent assay (ELISA) methods
- The client and bioanalytical laboratory had determined that the ELISA methods did not have the dynamic range to the range of concentrations expected following dosing of a peptide drug; this had led to multiple dilutions and emerging stability issues for the samples

APPROACH

 Development and validation of an LC-MS/MS method for the peptide solved the dynamic range, dilution and stability issues, particularly after a protease inhibitor cocktail was customized to enhance analyte stability

BENEFITS

 Although the method remained challenging to perform, the client was able to support their bioequivalence studies and make an application

See Other Case Studies

Mass Balance Study

Partnering with Biotechnology
Companies

EU Biotech Needs First-in-Human FDA Support

