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.