

## Customer case study

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### Project goal

Establish robust and sensitive methods for validation and quantification of large molecules in pharmacokinetic (PK) biomatrix samples, fingerprinting of biopharmaceuticals, and metabolite identification

### Biggest challenges

- Robust and sensitive methods to quantify PK samples after administration of new biological entities (NBEs)
- Analysis of intact mass of NBEs with >75% recovery from biomatrix
- Fingerprinting of large molecules and peptide mapping
- Low-level metabolite identification in biomatrices without false positives

### The solution

The X500B QTOF system from SCIEX could solve all 4 challenges. As a tabletop QTOF system, it is economical on space, and is robust without any specific requirements. We were able to develop robust and sensitive methods to quantify the PK samples after NBE administration, and the LLOQ was very good when compared to ELISA. In addition to being cost-effective, the system is very helpful for analyzing NBEs where no ELISA measures are present. We were able to analyze the intact mass of NBEs with >75% recovery from biomatrix.

### Outcomes of research

- Usage of BioPharmaView software led to successful fingerprinting of large molecules, peptide mapping and intact mass studies, which helped in understanding the purity of the proteins and their amino-acid sequence, which is a prerequisite to delineating target-based assays
- We were able to identify low-level circulating metabolites in biomatrix without false positives with confidence using the easy features of MetabolitePilot software
- In addition, the presence of the QTRAP 6500+ system helped in establishing the LLOQ in picogram levels for low biomatrix volumes and difficult chemistries such as target protein degraders, nucleotides and nucleosides

***"SCIEX is a partner in enabling the ease of doing research."***

***"SCIEX technology helped us in getting reproducible and robust results for our biopharma requirements and resulted in satisfied clients and more projects."***

### Type of organization

Aragen is a trusted R&D and manufacturing partner to the global life sciences industry. We transform your ideas into solutions for better health from concept to commercial.

### Goal

Aragen provides global resources and proven capabilities at every stage of the biopharma life cycle, in small and large molecules. Our ability to offer end-to-end solutions or support standalone programs is underpinned by an innovation mindset, enabling technologies and a partnership approach to every engagement.

Our belief—"In every molecule is the possibility for health"—motivates us to drive the success of our customers programs, so that we can together transform hope into health for millions of people around the world.

### SCIEX products

- API 4000 system (4 systems)
- SCIEX Triple Quad 4500 system (3 systems)
- QTRAP 4500 system (3 systems)
- QTRAP 5500 system (2 systems)
- SCIEX 5500+ system (2 systems)
- QTRAP 6500+ system (2 systems)
- X500B QTOF system