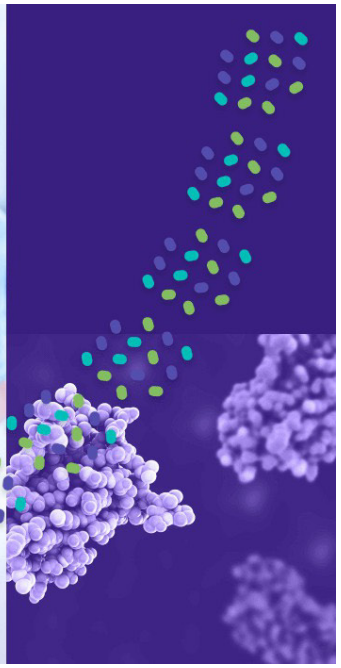
Excipient and contaminant testing boost the efficiency of drug substance lot evaluation.



Large Molecule Drug Discovery & Development Services:

After the tremendous effort of launching a drug product, ensuring its safety and efficacy through reliable release testing becomes paramount. Regulatory bodies are stringent about the active pharmaceutical ingredient (API), but their scrutiny intensifies when it comes to product specifications and potential contaminants introduced during manufacturing. At Prolytix, we deliver unparalleled scientific expertise to create customized, high-performance bioanalytical assays that support every stage of your product's lifecycle—from regulatory filing to stability and release testing. Trust Prolytix to safeguard your product's integrity and streamline your path to market success.

The Challenge:

Develop an HPLC assay capable of precisely measuring ammonium sulfate levels with exceptional speed, cost-efficiency, and superior resolution. This method was meticulously designed to meet the specific needs of the client's drug substance, ensuring unparalleled accuracy and a high degree of sensitivity.

Background:

In drug product and drug substance release, pH is a critical specification that directly impacts both financial outcomes and patient health. A subpar batch can lead to significant financial losses and jeopardize patients who depend on these therapeutics. When our client faced a deviation with their previous manufacturer, they sought a solution that not only met but exceeded expectations. They required a highly accurate, rapid, and dependable method for ammonium evaluation—not just for compliance, but to ensure the highest quality product for their patients. Our tailored assay delivers exceptional resolution to eliminate interference, while being fast, user-friendly, and cost-effective.

Client Challenge:

Prolytix was tasked with rapidly developing and validating an assay to measure ammonium concentration in the client's drug substance. The goal was to create a method free from the interference of ion-selective electrodes, more cost-effective than ion chromatography, and more sensitive than enzymatic analyzers. This assay would then be used to enhance the release evaluation of ammonium levels in the drug substance.

PROLYTIX Solution:

Prolytix experts employed IEX-HPLC to identify ionic contaminants, focusing on ammonium introduced during manufacturing from ammonium sulfate. Despite heavy interference from excipient signals, we achieved outstanding resolution and clarity with the sulfate peak, enabling a highly effective indirect analysis method. The ammonium content determined by our HPLC method was compared to that measured by an enzymatic analyzer, demonstrating excellent recovery and sensitivity down to 5 PPM. Our client was delighted to ensure their product's highest quality, and Prolytix was proud to contribute to their success with exceptional results.