Analytical Services for Sterile Drug Products

As a world class CDMO, we relentlessly strive to deliver better health outcomes for the patients we serve by combining our experience and expertise in science, manufacturing, and technology with our pristine customer service.

Analytical Services for Sterile Products

Through our GMP analytical testing laboratories, we will reduce supply chain complexity and expedite timelines, developing product-specific methods in-house or through the transfer of existing validated methods.

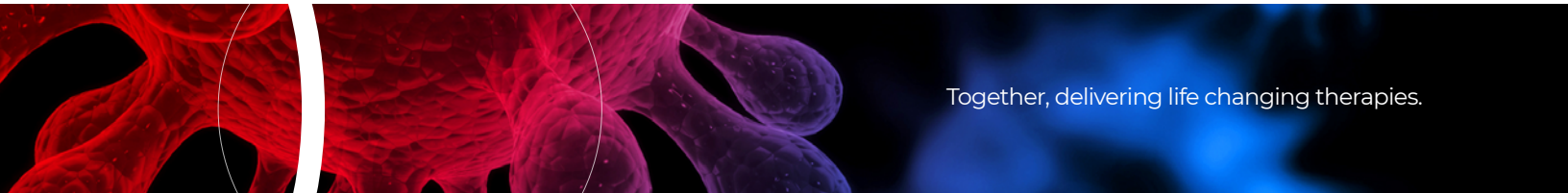
Our phase appropriate ICH validation approach for all analytical methods supports development, in-process, release, and stability testing. Our full-service laboratories are equipped with state-of-the-art instrumentation to meet testing requirements and we continually evaluate and expand our testing capabilities in-line with the growing needs of our clients.

Analytical Method Development

We provide a full analytical and Assay method development service utilizing our industry leading analytical equipment to efficiently meet your parenteral development needs, providing timely, reliable, and consistent results.

Analytical and Microbiological Testing Capabilities

- Gas chromatography (direct injection & headspace)
- Liquid chromatography – UPLC and HPLC
- FTIR
- UV/Vis
- Residual moisture by Karl Fischer
- Particle sizing
- Oxygen headspace analysis
- SDS-page
- Appearance
- pH
- Osmolality
- Density
- Reconstitution time
- Subvisible particulate matter (USP <788>)
- Extractable volume (gravimetric)
- Elemental impurities
- Anti-microbial Effectiveness Test (AET)
- Preservative Efficacy Test (PET)
- Bioburden
- Endotoxin
- Sterility
- Container closure integrity



Overview

ICH Stability Studies

At PCI, we will help you build, manage and, execute every aspect of your ICH stability program based on the specific requirements of your product.

This includes:

- Protocol development utilizing ICH stability guidelines
- All ICH conditions available in validated stability chambers
- Time point management and sampling by dedicated stability team
- Time point testing and data reporting with quality oversight
- Interim and final reports

ICH Q1B Photostability

We have the capability to perform non-GMP and cGMP photostability studies for drug substance and finished product.

This includes:

- Photostability protocol development utilizing ICH Q1B stability guidelines
- Storing products in validated photostability chambers at the recommended light intensity
- Time point management, time point testing, and data reporting with quality oversight
- Final report