



# Pharmaceutical Analytical Impurities

## Background

The global supply chain for medicines includes manufacturers and suppliers of drug products and their ingredients from around the world. Manufacturers must ensure that impurities in their drug products and their ingredients are properly detected and controlled regardless of who makes them and how they are produced.

## Opportunity to strengthen quality

Impurities are unavoidable in drug development and manufacturing. Even small changes to manufacturing processes can introduce new or elevated levels of impurities, which can harm patients. Thus, impurity analysis and profiling are critical during drug development and throughout the product life cycle.

## USP solutions

Pharmaceutical Analytical Impurities (PAIs) can be used by manufacturers in analytical testing to detect, identify, and measure impurities. PAIs are released through a USP quality process designed to help ensure identity and quality appropriate for analytical applications. PAI products are different from official USP Reference Standards, but together can help to provide a comprehensive solution for research and analytical needs across the drug lifecycle.

## Why it's important

Unsafe levels of impurities can pose a direct threat to patients and can prompt product recalls which can lead to drug shortages. Manufacturers need to control impurities to consistently produce safe and effective products, so patients have access to quality medicines when they need them. They can use PAI products and USP Reference Standards as part of their quality control strategies to help meet regulatory requirements.

## Web resources

- <https://go.usp.org/pharmaceutical-analytical-impurities>
- [USP eStore](#)