

Pharmaceutical Analytical Impurities



Controlling impurities in quality medicines

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

Thus, impurity analysis and profiling are critical during drug development and throughout the product life cycle.

Our new **suite of Pharmaceutical Analytical Impurities**, together with our portfolio of official USP Reference Standards, provides for a comprehensive solution to your research and analytical needs for therapeutic classes including:

- Analgesics
- Antihyperlipidemics
- Gastrointestinal
- Psychiatric
- Antibiotics
- Cardiovascular
- Oncology
- Steroids

... and many more as we expand our product line

PAI products are different from official USP Reference Standards. They are released using a separate process developed by USP's subject matter experts. The release process follows rigorous internal policies, standard operating procedures, and USP Quality Management System requirements. USP is an ISO 9001:2015 certified facility.

Applications in drug development and throughout the product lifecycle

Pharmaceutical Analytical Impurities (PAI) products along with the batch-specific product information sheets can help you save time and resources and mitigate risks associated with quality and consistency. They can be used in the following potential applications:

- Conduct analytical tests during early formulation feasibility studies.
- Perform spiking studies during process R&D to demonstrate depletion upon recrystallization.
- Identify or confirm peaks by comparing retention times and/or spectra.
- Determine relative response factors.
- Determine degradation impurities produced during stress studies.
- Identify unknown impurities that formed during ICH stability conditions.
- Identify impurities which are present in the Reference Listed Drug.
- Develop, validate and transfer analytical methods.
- Release Active Pharmaceutical Ingredients (API) or drug products by testing for impurities not listed in monographs.

Learn more

To learn more about USP's Pharmaceutical Analytical Impurities or to provide input on future PAI products, please visit:



<https://go.usp.org/pharmaceutical-analytical-impurities>



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