Impurities for Development
The Pharmacopeial Advantage™
Impurities for Development

As a global leader of standards for quality medicines, USP has provided the broadest spectrum of official standards and support resources for nearly 200 years. Now, we have expanded our independent and trusted processes to offer a new service: Impurities for Development (IfD).

Our new robust service identifies, isolates, synthesizes and characterizes impurities in medicines under development, giving you confidence and control to efficiently deliver quality medicines to market.

When you need to be sure about impurities, trust USP.

The molecular structure of Hydantoin aminoalcohol on the front cover is for illustrative purposes only. Hydantoin aminoalcohol is one of the many impurities that can be identified, isolated or characterized with the Impurities for Development program.
Accurate insights to produce quality medicines

Manufacturers have to ensure the quality and consistency of ingredients that go into a final pharmaceutical product. Impurities can occur naturally within the source materials, be added intentionally as part of a product’s synthesis, be introduced inadvertently during processing and manufacturing, or form during the shelf life of the product. As a result, manufacturers have to deal with many impurities-related demands during the development cycle, including:

- Prediction of likely impurities
- Detection, identification, quantitation and characterization of impurities
- Control of impurities levels or degradation products
- Compliance with regulatory expectations
- Validation or verification of analytical procedures and demonstration of their suitability for detecting and quantitating impurities
- Establishment of acceptance criteria based on safety considerations and consistent with current regulatory guidance

USP’s Impurities for Development services give you confidence and control when characterizing impurities
A customized approach

Our highly qualified team of scientists puts their expertise in process and synthetic chemistry to work for you in state-of-the-art, ISO-accredited facilities. We will tackle a wide range of impurities-related challenges that surface during manufacturing and process optimization—especially impurities without available standards. We take a flexible, adaptive approach, and offer a range of services to meet your specific needs:

**Identification**—structural and material characterization

When provided with a sample of unknown impurities, we will create a tailored set of spectroscopic, chromatographic and/or other analytical techniques to identify and characterize it. We can also verify the identity of an impurity that you have tentatively identified.

**Isolation and characterization**—degradation impurities, process impurities, drug candidate impurities

For a mixture containing an impurity, we isolate a small amount of pure sample and characterize it to determine its identity. Samples can be provided for future analytical testing.*

**Synthesis and characterization**—new API impurities, non-USP catalog impurities

We apply our experience developing quality Reference Standards—including impurities—to synthesize impurities typically not available in USP’s catalog.

*A Certificate of Analysis (CoA) and characterization data package are provided to confirm the identity of each impurity. Samples are not official USP Reference Standards and are not intended for therapeutic use.
when it comes to impurities

quality counts
We’re with you at every step

Impurities for Development is unique because it provides your development team with real-time expertise in impurity evaluation throughout the product life cycle, allowing you to focus on other development processes. Each IfD service is developed for your specific drug product and is custom-designed to meet your needs.

USP is the first and only pharmacopeia to offer these kinds of impurities services. We are with you because we share a common goal: quality medicines.

The Impurities for Development service is not just about impurities. It is about ensuring the development of quality medicines and building a healthier world.
You can expect our new Impurities for Development service to:

- Deliver quality-assured impurities with multilevel quality checks
- Help you build pharmacopeial compliance into every step of the drug development process
- Verify identification and execute isolation of impurities to meet different requirements
- Help you produce hard-to-source complex impurities that are not available commercially

- Provide on-demand synthetic capabilities
- Help to ensure the quality of your medicines over their development life cycle, including purity, strength, identity and performance
- Leverage USP’s unique combination of experience and expertise at every level of the pharmaceutical product development cycle
- Increase confidence and trust in the quality of your drug products