

Setting the Benchmark in Pharmaceutical Standards



## About Us

At ISP Standards, we are at the forefront of pharmaceutical safety and innovation. In today's world of rapidly evolving drug formulations and increasingly intricate global supply chains, we tackle the critical challenge of impurity control with precision and expertise.

Our mission is to ensure the safety, efficacy, and integrity of medicines worldwide. Through cutting-edge solutions, scientific rigor, and an unwavering commitment to quality, we empower pharmaceutical companies to deliver safer medicines. Together, we redefine excellence in pharmaceutical standards and safeguard global health.

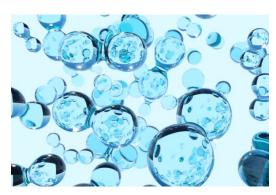
## OUR ROLE

We specialize in manufacturing and supplying pharmaceutical reference materials, including:

- API Reference standards and Working standards
- API Impurities
- API Intermediates
- Nitrosamine Impurities
- Pharmacopeia Reference standards (IP,BP,EP and USP)
- CRM Mixtures
- Stable Isotope Labelled Compounds
- GC, GCMS and ICPMS standards
- Organic, inorganic and Pesticides mixtures for water analysis



## Our Strengths



# Driving Innovation in Reference Standards

ISP Standards invests in cutting-edge R&D to develop pioneering solutions for impurity detection and synthesis. Our focus on innovation ensures our clients stay ahead in an evolving pharmaceutical landscape.

### Global Reach. Local Expertise.

ISP Standards serves clients worldwide, delivering products and services tailored to diverse regulatory environments. Whether you're a small-scale lab or a multinational pharma giant, we scale to meet your needs..



## What Sets Us Apart



### 40,000+ Products

derived from over 750 APIs



#### **Highly Qualified Team**

MSc & PhD chemists with decades of synthesis expertise



#### **Comprehensive Certification**

COA, IR, Mass, HPLC, NMR, TGA & ROI



#### In-house Analytical Capabilities

Ensuring all tests meet global standards



#### Traceability

USP/EP traceable products available on demand



#### Uncompromised Quality

Every product meets stringent quality standards



#### **Technical Support**

Extensive assistance for all your analytical needs



### Detection, Synthesis, and Analysis of Pharmaceutical Impurities

Identifying impurities is the first step in preventing them. By elucidating their structure, it is possible to understand their formation mechanism, which informs industry practices around prevention and control.

### **Comprehensive Impurity Analysis**

For impurity identification, drug components must be separated to isolate process contaminants, degradants, or leachables alongside the active pharmaceutical ingredients (APIs). ISP Standards employs state-of-the-art instrumentation for this process, including:

- High-Performance Liquid Chromatography-Mass Spectrometry (LC-MS): For less volatile impurities
- Gas Chromatography-Mass Spectrometry (GC-MS): For more volatile impurities
- Nuclear Magnetic Resonance (NMR) Spectroscopy and Fourier-Transform Infrared (FTIR) Spectroscopy: To identify impurities at the molecular level

Different combinations of techniques are used case-by-case, depending on the compound's complexity and customer requirements. We provide fully characterized pharmaceutical impurities with detailed Certificates of Analysis (CoA), including data such as:

- 1H-NMR, IR, Mass, HPLC Purity
- Additional data on request: 13C-NMR, COSY-NMR, TGA, CHN Analysis, and more



## Our Expertise

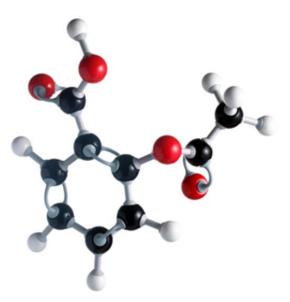


#### **Custom Synthesis Services**

From milligrams to kilograms, we deliver precision with innovative synthetic route development and expert project management.

#### **Nitrosamine Reference Standards**

Ensure the safety of your drug substances with our reliable and accurate nitrosamine testing standards.





#### **Purification Services**

We offer complete purification and analytical support for the production of pharmaceutical and functional products, leveraging our years of expertise in purification technology for any scale, from small to large production runs.



## Why Choose ISP?



### **Excellence Redefined**

At ISP, we go beyond the standard. Every aspect of our offering—knowledge, quality, scientific intellect, and transparency—defines our commitment to delivering high-quality pharmaceutical reference standards you can trust.



#### **Comprehensive Solutions**

From impurity profiling and working standards to logistics and inventory management, we provide a wide range of collaborative services tailored to your needs.



### **Confidence in Every Step**

Our certified products and real-time support give you confidence, from characterization to implementation, ensuring your analysis is always accurate and reliable.



#### **Innovation Meets Expertise**

Combining decades of experience with continuous training, we ensure our reference standards are produced using the latest techniques and regulatory insights.

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