eurofins | BioPharma Product Testing

Reference Standards & Materials – Simplifying Your Laboratory Work

Added Value of Original Pharmacopoeia Standards from Eurofins PHAST

Eurofins PHAST offers over 9,000 Reference Standards officially recognised by regulatory authorities, ensuring compliance in your laboratory. Beyond these standards, USP provides additional Reference Materials designed to simplify daily lab work.

USP Analytical Reference Materials (ARM)

USP Analytical Reference Materials are characterised substances with supporting data, suitable for various pharmaceutical applications:

- **For Active Pharmaceutical Ingredients (APIs)** that are not marketed in the U.S. and lack USP monographs, ARM provides reliable alternatives.
- **ARM** can also support the development of complex generics or APIs where no USP monographs exist.

These materials play a crucial role in quality assurance worldwide, supporting analytical testing, research, and the evaluation of raw materials, laboratory equipment, and other components used in the pharmaceutical, food, and supplement industries.

USP Reference Standards for Impurities

Impurities discovered during manufacturing or in-market products can lead to costly recalls and regulatory actions. Impurities may arise at any stage of production, during transport, or storage.

Early use of **USP impurity standards** helps control impurity levels throughout the product lifecycle, minimising risks of delayed approvals or batch recalls.

USP Nitrosamine Impurities

Elevated levels of **nitrosamines**, known potential carcinogens, have been found in several commonly prescribed medications. Newly identified **Nitrosamine Drug-Substance Related Impurities (NDSRIs)** have further complicated regulatory challenges.

To assist manufacturers and regulatory agencies, USP introduced **General Chapter <1469>** in the **United States Pharmacopeia (USP)**, providing guidelines for assessing nitrosamines and implementing appropriate control strategies. Additionally, USP has developed approximately **30 nitrosamine Reference Standards** and Pharmaceutical Analytical Impurities (PAI), now available for industry use.

USP Pharmaceutical Analytical Impurities (PAI)

Alongside monographed impurity Reference Standards, USP offers a growing catalog of **non-monographed impurities** under its **Pharmaceutical Analytical Impurities (PAI)** product line.

Manufacturers conduct risk assessments to identify and evaluate potential impurities that may arise during production. Even in trace amounts, impurities can impact drug efficacy or cause adverse effects.

USP's **PAI portfolio** significantly simplifies impurity identification across various applications:

- Research & Development (R&D)
- Method Development
- Manufacturing
- Quality Control
- Stability Testing
- Post-Market Monitoring

USP Reference Standards for Excipients

Excipients, though inactive, can constitute up to **90% of a drug formulation**, making their quality critical to product safety and efficacy.

- **Documentation Standards** define validated testing procedures for identity, purity, and quality.
- **Reference Standards** serve as official benchmarks for comparison.

Easy & Convenient Ordering

USP Reference Standards are available for quick and easy ordering via:

- **Webshop:** www.reference-standards.com – Register with a one-time code for pricing and cart functionality.
- **Email:** Request a quote or place an order (PDF) via reference-standards@bpt.eurofinseu.com.

If you require a **Reference Standard not listed** in the webshop, please contact: reference-standards@bpt.eurofinseu.com.

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Comprehensive GMP Testing Services

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