Confidence in managing your path

Your benchmark for quality

You're getting more than just a vial when you purchase an official USP Reference Standard. You're getting the confidence of knowing that you have a trusted entity that offers a unique combination of standards, process and service to help you on your journey to regulatory compliance. Our quality standards are the industry benchmark because of the robust scientific process, the unparalleled service and knowledgeable, expert advice that USP offers you throughout the development process.

We offer the largest collection of 3,700 highly characterized Reference Standards, most directly tied to documentary standards. USP creates official, quality standards for medicines that are enforceable in the United States and used in more than 140 countries.

We give you confidence as you manage the increasing demands for quality on your path to compliance.

3,700+

USP offers the largest collection of highly characterized Reference Standards, including more than 1,600 impurities, most directly tied to documentary standards.

Minimize your risk with our comprehensive approach

Trust the quality standard that sets the benchmark for medicines worldwide. USP offers official methods, specifications and associated Reference Standards that can help your product meet regulatory requirements and patients' needs.

Quality standards

Rigorously tested and highly characterized - USP Reference Standards undergo a rigorous process of scientific characterization by multiple independent laboratories around the world. Our standards provide more than scientific guidelines; they give you confidence in your approach throughout the product life cycle.

Robust scientific process

Independent volunteer science experts - USP convenes volunteer experts and leaders from industry, healthcare, academia and regulatory authorities to discuss, debate and approve standards. You can join other industry stakeholders to contribute to the process by sharing your perspectives, insights, questions and concerns during the standards development process.

Unparalleled service

A holistic approach to customer support - Our knowledgeable global representatives, scientific liaisons and technical support and customer service teams are available to provide information and answer questions to guide you throughout your Reference Standard user experience. Online and onsite training and education provide direction on using official USP Reference Standards effectively. Topical resources that address specific challenges are available to help you succeed. We provide answers when you need them.

80%

percentage of customers surveyed who rate USP Reference Standards as “best in class”

Where *USP* or *NF* tests or assays call for the use of a USP Reference Standard, only those results obtained using the specified USP Reference Standard are conclusive

– USP–NF General Notices Section 5.80

USP standards: quality you can trust

Using USP official Reference Standards can reduce the time and resources that you need to invest in developing in-house standards and can facilitate compliance with regulatory requirements. Our standards provide precise testing and validation guidelines, as well as reference samples for testing, so that drugs can be made consistently, every time.

Primary reference standards obtained from an officially recognized source are normally used without testing if stored under conditions consistent with the supplier's recommendations.

– ICH Q7

Reference Standard development process

Multiple lab testing

USP Reference Standards are thoroughly characterized by a variety of methods. Tests conducted by multiple laboratories improve the confidence in the assigned value by addressing real-life inter-lab variability in measurements.

Comprehensive analysis

Committees of scientific experts from government, industry and academia independently review and evaluate USP standards to help ensure accuracy and provide a trusted reference for analytical testing.

Continued suitability for use

Ongoing testing eliminates the need for an expiration date and helps ensure the quality of your product over time.

Standards tied to monographs

- Antivirals
- Antimicrobials
- Antibiotics
- Cardiovascular
- Cough & cold
- Analgesic
- Gastrointestinal
- Impurities
- Endocrine
- Ophthalmology
- Pulmonary
- Dermatology
- Excipients
- Oncology
- Steroids
- OTC
- Renal

4,900

number of official monographs that link directly with a Reference Standard

Only USP Reference Standards are linked to 4,900+ official *USP–NF* monographs that provide specifications for the identity, purity and potency to meet compliance requirements for FDA-approved drugs. Monographs for drugs, excipients, biologics and compounded preparations include specifications for identity, strength, quality, purity, packaging and labeling.

USP Reference Standards have official status when used with the compendial standard. They do not need to be compared or evaluated against any other standard; a CoA is not required for use.

Expert, independent volunteers

Independent volunteers, who are selected based on their knowledge and experience, review laboratory analyses and develop monographs and general chapters before they are published for public review and comment. These independent experts consider the public feedback and finally approve the monographs and general chapters before they are added to the *USP–NF*.

350+

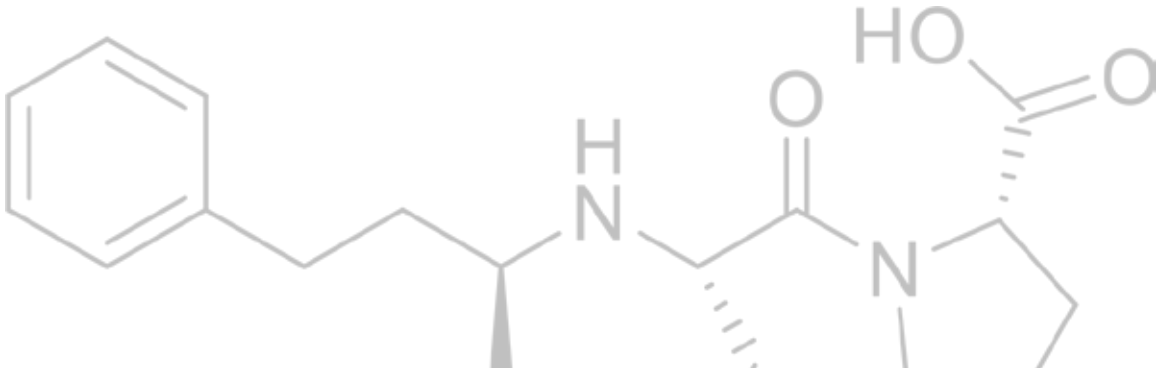
general chapters with clear, step-by-step direction for assays, tests and procedures.

875+

volunteer experts from academic, commercial and government institutions, health practitioners, science associations and consumer organizations around the world.

USP

is the only organization that can produce Reference Standards linked to *USP–NF* monographs to help meet compliance requirements.



2 Adding value to your drug manufacturing process

USP standards can be a strategic advantage as part of your pharmaceutical production process. From raw materials to product development, to manufacturing, to finished products and beyond, these are just some of the ways you can leverage our products, services and support to efficiently bring your products to market.

Raw materials – Suppliers may declare their raw materials conform to USP standards when they meet compendial specifications. Such indications of a supplier's quality program can simplify your supplier selection process.

In process – The compatibility of the ingredients that comprise the final dosage form is critical to its quality. USP Reference Standards help minimize the risk of poor-quality materials affecting in process testing, by improving the accuracy of blend uniformity and helping to ensure consistency from batch to batch.

Release testing and stability studies – Using USP Reference Standards during release and stability testing can help improve your confidence in test results.

USP redefines service

Service at USP means access to the in-house scientific experts who help develop the standards, world-renowned training and education, global technical and customer teams and many unique resources to help you succeed. USP has the support you need to help achieve the results you want and regulatory agencies require. We deliver outstanding ongoing support and training globally and pride ourselves on our customers' satisfaction.

From buying to applying, we're with you every step of the way

Resources

We provide a variety of tools to assist you in your work at www.usp.org

- **New *USP–NF Online*** – the most up-to-date monographs and general chapters, including all of the 4,900 monographs for drug substances, dosage forms, excipients, biologics and compounded preparations, with specifications for identity, strength, quality, purity, packaging and labeling
- **Reference Standards App** – easily access, track and receive notifications, alerts and updates on USP official Reference Standards from any mobile phone or tablet
- **Dissolution** – The USP Performance Verification Test (PVT) is an integral part of General Chapter <711> *Dissolution* and assesses proper dissolution apparatus performance. PVT is a holistic test; by using the reference standard material and the standard procedure, laboratories can compare results from their instruments with other laboratories worldwide. Guides, training and tip sheets are available at usp.org
- **Chromatographic columns** – a database that contains the brand names of all chromatographic columns used in USP tests and assays
- **USP Store** – online access 24/7 for all your USP purchasing needs
- **Safety Data Sheets** – safety information for the complete catalog of USP Reference Standards

1,100+

employees around the world,

including scientific liaisons, technical support experts, customer service representatives and a knowledgeable and responsive sales team

50,000+

have attended online and on-site training, workshops, user forums, courses and webinars in the past eight years

USP SERVICES

Programs

- **USP Education** – educational programs on how to effectively use USP's internationally recognized quality standards. Courses are presented by approved instructors with practical, firsthand knowledge of the subject area and related standards.
- **New Impurities for Development (IfD)** – a new program delivers customized solutions to identify, isolate, synthesize and characterize impurities not listed in the USP catalog that occur in medicines under development. IfD delivers confidence to pharmaceutical manufacturers when characterizing impurities in their effort to deliver quality medicines efficiently to market.
- **Ingredient Verification Program** – evaluates ingredients for identity, strength, purity and quality through rigorous testing, review of quality control and manufacturing documentation and GMP auditing processes.

Global Support

Our global support network can help guide you from buying to applying our quality standards and provide accurate and timely information in person, over the phone or online. Our in-house scientific liaisons can answer questions regarding specific USP standards. These liaisons are part of the teams that develop our monographs and general chapters. You also have access to our knowledgeable and responsive customer service experts to answer questions in multiple languages, including English, Korean, Mandarin, Italian, Spanish, French, German, Hindi (several Indian dialects), Russian, Japanese and Arabic.

USP is more than standards. We are a trusted resource that offers a unique combination of standards, process and service to help you on your journey to regulatory compliance. Talk to us about Reference Standards and find out how we can help you navigate your path to compliance.

Find us on:

Facebook: /uspharmacopeia

YouTube: /uspharmacopeia

Twitter: /uspharmacopeia

LinkedIn: /company/uspharmacopeia

PMRC-126.00 8/2018

usp.org