Uses of USP Reference Standards

USP Reference Standards are integral components of monographs and other documentary standards established by USP to help ensure the identity, strength, quality, and purity of medicines and foods, and are provided primarily for quality control use in conducting the assays and tests in these documentary standards. USP Reference Standards are specified for use in pharmacopeial assays and tests in the official standards publication, the *United States Pharmacopeia–National Formulary (USP–NF),* and help ensure compliance with the official, FDA-enforceable quality requirements in the *USP–NF*. USP Reference Standards are specified for use in the effective monographs of the *Food Chemicals Codex*. USP Reference Standards also lend themselves to other applications, including measurements required to obtain accurate and reproducible results in modern chromatographic and spectrophotometric methods. USP Reference Standards are not to be used as drugs,dietary supplements, or medical devices. To serve its intended purpose, each USP Reference Standard must be properly stored, handled, and used. Users of USP Reference Standards should refer to General Chapter <11> in the *USP–NF*.

Rigorous Testing and Quality Control

USP Reference Standards are selected for their high purity, critical characteristics, and suitability for the intended purpose. For quantitative Reference Standards, assigned values can be found on the label. If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. This applies only to USP Reference Standards intended for quantitative use in USP compendial procedures. The assigned value is not applicable for qualitative uses. Please refer to a USP Reference Standard's USP compendial application(s) to determine if the Reference Standard is used qualitatively and/or quantitatively.

USP Reference Standards are established through a process of rigorous testing, evaluation, and quality control. They are collaboratively tested in multiple laboratories. The Reference Standards are released under the authority of USP's Board of Trustees.

Reference Standards Categories

USP offers more than 3,600 Reference Standards for pharmaceuticals, excipients, dietary supplements and food ingredients. This website features a full list of available USP Reference Standards, with information updated daily. The list includes:

- Reference Standards specified by the current official edition of the *USP–NF*
- Reference Standards specified by Pending Monographs and Non-U.S. Monographs
- Reference Standards specified in proposed revisions to *USP–NF* or *FCC* and published in the *Pharmacopeial Forum* or *FCC Forum*
- Reference Standards specified in the current edition of the *Food Chemicals Codex*
- Reference Standards for substances of abuse, required by analytical, clinical, pharmaceutical and research laboratories

The distribution of controlled substances is subject to the regulations and licensing provisions of the Drug Enforcement Administration of the U.S. Department of Justice. USP also collaborates with the World Health Organization in its program to provide international biological standards and chemical reference materials for antibiotics, biologicals, and chemotherapeutic agents. Some USP Reference Standards are standardized in terms of the corresponding international standards.

Where to Find Information on *USP–NF* Reference Standards

- Individual *USP* or *NF* monographs as well as certain General Chapters specify the USP Reference Standard(s) required for assay and test procedures. General Chapter <11> USP Reference Standards provides general information and instructions for proper use and storage. Consult the label text and USP Certificate for proper use and handling of individual Reference Standards.
- For updates on specific USP Reference Standards, you may consult the Reference Standards Information section of the Official Text web page at **www.usp.org/usp-nf/official-text** and the USP Monthly Email Notices at **www.usp.org/store/services-and-resources/email-notice**.
- For the most up-to-date availability and lot information, please consult our online store at **www.store.usp.org**.
- Answers to several Frequently Asked Questions are available on our website at **www.usp.org/frequently-asked-questions/reference-standards**.

Suitability for Use

- Users must ascertain that the Reference Standards they are using are from a valid lot.
- Users must determine the suitability of Reference Standards for applications and uses not in the *USP–NF, Food Chemicals Codex* or *USP Dietary Supplements Compendium.* Any non-compendial use is at the purchaser's sole risk and expense.

Storing

- Ensure that the USP Reference Standards are stored in their original stoppered containers, according to any special label directions, away from heat and humidity, and protected from light. The storage condition for an unopened USP Reference Standard can typically be found on the container label. Storage conditions are no longer provided in the Safety Data Sheets (SDS). Instead, the SDS refers users to the USP Reference Standard label. Storage conditions are lot-specific and may change from one lot to another. If no specific directions or limitations are provided on the USP Reference Standard label, the conditions of storage shall include storage at room temperature and protection from moisture, light, freezing and excessive heat. Refer to General Chapter <659> Packaging and Storage Requirements in the *USP–NF* for definitions of storage and handling terms.

Weighing

- Ensure that Reference Standard substances are accurately weighed—taking due account of relatively large potential errors associated with weighing small masses—where it is directed that a standard solution or a standard preparation be prepared for a quantitative determination. See the current official edition of *USP–NF* General Chapters <41> Weights and Balances and <31> Volumetric Apparatus, and *USP–NF* General Notices for information regarding appropriate use of USP Reference Standards.

Drying

- Use a clean and dry vessel, and not the original container, as the drying vessel where a USP Reference Standard is required to be dried before use.
- Make sure not to dry a specimen repeatedly at temperatures above 25 degrees Celsius.
- Follow any special drying requirements specified on the Reference Standards label, USP Certificate or in specific USP compendial monographs.
- Follow Method I under *USP–NF* General Chapter <921> Water Determination where the titrimetric determination of water is required at the time a Reference Standard is to be used. Instrumental or microanalytical methods are acceptable for this purpose. When using typical amounts, about 50 mg of the Reference Standard, titrate with a two- to five-fold dilution of the reagent.

How to Read Product Listings

Column 1 (Catalog Number): Catalog number currently assigned to each Reference Standard. ***Please include this number in your order.***

Column 2 (Description): Product description as designated in the USP publication being referenced, the product label, and/or the Drug Enforcement Administration Control Schedule, as applicable. (All materials are in single containers unless otherwise specified.)

Column 3 (Current Lot): Current lot designation of each official item being distributed as of the "Last Updated On" date of the catalog being referenced. If the current lot is blank, the item is not in distribution.

Column 4 (Previous Lot/Valid Use Date): Lot designations for recent lots no longer being distributed.

Column 5 (CAS Number): Chemical Abstracts Service number, when available, for USP Reference Standards. CAS number is for information only. USP does not assign CAS numbers to chemicals, numbers are assigned by the Chemical Abstracts Service which is a division of the American Chemical Society. USP information should not be used to assign CAS numbers.

Column 6 (NDC Number): National Drug Code at USP—An 11 digit (3 Segment) number that is a product identifier used to distinguish controlled substances at USP for DEA reporting purposes. The first segment (Labeler Code) identifies the company, the second segment (Product Code) references the product, and the third segment (Package Code) indicates the package size.

Column 7 (Price): List price of the Reference Standard.

Column 8 (Special Restrictions): Lists any special shipping or ordering conditions for an item.

USP Reference Standards Catalog Formats

USP offers the following Reference Standards Catalog options:

- **USP Reference Standards Catalog:** Online PDF and Excel listing of USP Reference Standards that is updated daily. English only. View at **www.usp.org/rs-catalog**
- **USP Store:** For the most up-to-date USP Reference Standard lot listings, and to purchase Reference Standards, please visit our online store at **www.store.usp.org**.