Use and Storage of USP Reference Standards

To serve its intended purpose, each USP Reference Standard must be properly stored, handled, and used.

Ascertain Valid Use

Users are responsible to ensure that the Reference Standards they are using have official status either a "Current lot" or as a "Previous lot" within the valid use date. Current and previous lot information is available in the USP Catalog.

Directions on the label of the Reference Standard

Directions for storage and use are on the label of each Reference Standard. These directions are lot-specific and take precedence over any other indications in the USP–NF. The label includes safety warnings, required information for controlled substances, and calculation values for standards with quantitative applications. For calibrators, acceptance ranges are provided. Where necessary, USP Reference Standards are shipped with additional technical data sheets.

Directions in USP-NF

Æ

Refer to the list of revisions, additions, and deletions of individual USP Reference Standards in USP–NF. Individual USP or NF monographs specify the USP Reference Standards required for assay and test procedures. The USP–NF General Test Chapter <11> USP Reference Standards provides additional information and instructions for proper use and storage.

Æ

Consult the cumulative updates to Reference Standards information provided in USP–NF Supplements and also in USP–NF Interim Revision Announcements, which are published in USP's bimonthly journal, Pharmacopeial Forum.

Storing

Æ

Ensure that USP Reference Standards are stored in their original stoppered containers away from heat and humidity and protected from light. Follow any special label directions. (View USP's policy statement on the storage and usage of Reference Standards. (A (61KB))

Weighing

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

Drying

Where a USP Reference Standard is required to be dried before being used, use a clean and dry vessel—and not the original container—for drying.

Make sure not to dry a specimen repeatedly at temperatures above 25 degrees.

Follow any special drying requirements specified on the Reference Standards label or in specific sections of USP or NF monographs (note that any specific instructions on the label or in the monograph supersede the usual instructions in Procedures under Tests and Assays in USP–NF General Notices).

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 fourfold dilution of the reagent.