# Frequently Asked Questions

## Use and Applications

**Are USP Reference Standards suitable for use as drugs or medical devices?**

USP Reference Standards are intended for test and assay use only; they are not intended for administration to humans or animals as drugs or medical devices. View USP's policy statement on the (3)[storage and usage of USP Reference Standards](#) (61KB).

**Are USP Reference Standards suitable for applications not specified in the USP–NF?**

You may be able to use USP Reference Standards for analytical or laboratory applications other than those specified in the USP–NF, but you are responsible for determining the suitability of the standards for the required purposes. USP Reference Standards may not be used as drugs or for diagnostic purposes.

**How do I determine if a Reference Standard has expired or is still valid for use?**

To determine the current status of a USP Reference Standard, please consult the [official USP Reference Standards Catalog](#), published bimonthly online and every four months in print. USP Reference Standards do not carry expiration dates in the traditional sense. Rather, they are granted Official Status under the authority of the United States Pharmacopeial Convention Board of Trustees upon recommendation of the USP Reference Standards Expert Committee. (View USP's policy statement on (4)[expiration dating of USP Reference Standards](#) (62KB).)

If the lot number indicated on the label of your Reference Standard matches the number in the Current Lot column of the product listing or catalog, it means that your Reference Standards are valid for use. If the Reference Standard you are using is not from the current lot, check the Previous Lot/Valid Use Date column. This column identifies the expiration dates for lots no longer being distributed. The last day of the indicated month represents the expiration date for the specified lot (e.g., "F–1 06/02" means lot F–1 was considered official through June 30, 2002).

**How long is the previous lot valid for use after a new lot is developed?**

Please consult the [official USP Reference Standards Catalog](#), published bimonthly online and every four months in print. Two columns appear in the catalog to identify the current official lots. One column identifies the official lot currently being shipped by USP. If the field is blank, then the current lot is not in distribution. In some cases, the previous lot may still be considered official. If this is the case, it is identified in the second column. Ordinarily, the previous lot is carried in official status for one year after the current lot has been depleted, unless the previous lot is found to be no longer suitable for its intended use because of a change in monograph requirements or stability limitations. The catalog indicates the month and year through which previous lots may be used. (View USP's policy statement on (4)[expiration dating of USP Reference Standards](#) (62KB).)

**Do USP Reference Standards require any special preparation before use?**

Any specific directions for storage and use are provided on the label of the Reference Standard. Some standards can be used as–is but others may require drying before use or correction of the labeled valued with a concurrent moisture or Loss on Drying determination. Additional information on special preparation requirements for USP Reference Standards may be found in General Chapter <11> USP Reference Standards. See (5)Use and Storage for more details.

**Why is USP not requiring annual recertification of the USP Near Infrared System Suitability Reference Standard?**

The USP Near Infrared System Suitability Reference Standard does not require recertification because of a combination of the component material, a proprietary housing and seal, and USP's commitment to a continuous suitability for use program. For more details, download our （6）official statement（NIR No Recertification Letter） (106KB).