Not all standards are created equal

usp®

In today's climate of supply-chain modifications and shifting priorities resulting from the COVID-19 pandemic, insistence on high pharmaceutical manufacturing standards is more critical than ever. USP is a leading standards-setting organization that makes upholding quality easier. In addition to documentary standards (monographs, general chapters), USP produces physical Reference Standards that offer a variety of advantages over secondary and other in-house or commercial standards. First, there's the robust and collaborative process we go through to develop our standards. Additionally, we take care of proper characterization and lot expiration tracking, and test for continued suitability for use. Our preparation enables companies like yours to be more efficient in the laboratory because this work has already been done for you.

And if you have questions about test methods, calibrations, or other processes you use to ascertain consistency with the standards, we at USP are ready to support you with technical advice and educational resources. USP is here for you — fulfilling our mission to improve global health through public standards and programs that help ensure the quality, safety, and benefit of medicines.

Your peers report advantages to using pharmacopeial standards

Recently published USP survey results and research by Johns Hopkins University provide new evidence that choosing pharmacopeial documentary standards and physical Reference Standards has clear benefits. The 92 generic drug manufacturers who participated in the survey responded that the use of compendial standards:

- **Accelerates product development:** Generic drug companies save 19% of overall development time, and 31% of analytical method development time
- **Reduces the risk of ANDA rejection:** 90% of generic drug company respondents believe that the use of pharmacopeial products reduces the risk that the FDA will reject their ANDAs

This survey suggests that USP Reference Standards and monographs make it easier for drug manufacturers to develop generic versions of off-patent drugs — which benefits patients everywhere.

What all this means for you

As a standard-setting organization in the pharmaceutical industry, we at USP understand that your quality processes are complex and highly regulated — and compliance and patient safety are top priorities. On the flip side, you need to run your lab efficiently and cost effectively, always with an eye on minimizing risk, while balancing these needs with the importance of getting to market quickly. One way to achieve all these goals is by using USP Reference Standards and monographs.

Skip characterization

Using USP Reference Standards and monographs will allow your organization to save time and resources by eliminating the work of properly characterizing your other standards, as required by the local regulatory authority. Simply testing a material against a monograph is not sufficient to establish a reference standard for compendial compliance testing. USP has properly characterized its Reference Standards for you.

Achieve conclusive results

Only results obtained through the combination of a USP physical Reference Standard and documentary standard are regarded as conclusive. For example, as secondary standards are developed and consecutive measurements are taken, the uncertainty associated with each measurement result increases (Fig. 1). What's more, you do not even know the extent of that uncertainty. And if there is ever an issue with your product, there is the risk that the local national lab will test it against a USP Reference Standard to obtain the compendial and conclusive result.

Avoid stability testing

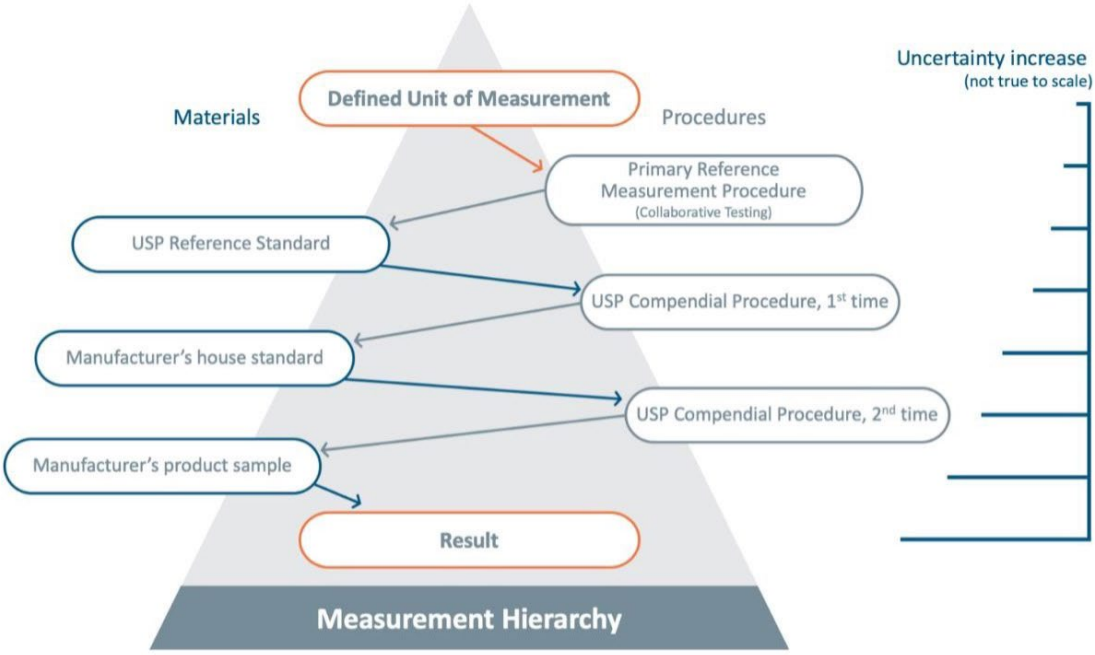
USP's continuous suitability for use testing provides confidence in the quality of your USP Reference Standards by defining their valid use periods. Otherwise, you will need to have an ongoing stability testing program in place for secondary standards in your storage area to ensure they retain their integrity.

Bypass additional lot expiration tracking

If the pharmacopeial reference standard lot is outside its valid use period, any secondary standard it is used to validate also becomes invalid. By using a USP Reference Standard, you bypass the need to set up internal controls to track lot expiration of any secondary or reference standards created in-house.

Be confident in your choice

Quality and quality systems are important and challenging components of the pharmaceutical industry and critical for patient safety. The ramifications of any product or system failure could result in patient harm or lack of benefit, launch delay, product withdrawal, or production line closure. Choosing the right reference standards can help to mitigate these potential risks while achieving your goals as effectively and efficiently as possible.



REFERENCE

[1](Fig. 1) USP Council of Experts, USP Reference Standards Committee, Hauck WW. Primary and Secondary Reference Materials for Procedures to Test the Quality of Medicines and Foods. Pharm Res. 2012 April;29(4):922-931. doi: 10.1007/s11095-012-0687-7.