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General

Does USP issue Certificates of Analysis (COAs) for USP Reference Standards?

With the exception of CRMs, USP does not provide COAs. All information for official uses of a Reference Standard is on the label of the standard and where needed, in the additional data sheets shipped with the standard. USP does provide Material Safety Data Sheets (MSDS) for all Reference Standards and USP Certificates for some Reference Standards. USP Certificates do not completely describe the test results obtained during evaluation for scientific and legal reasons. Rather, the certificates are issued to provide customers with a hard copy of the USP label text of the standard. These certificates, when available, can be viewed on our Web site by clicking on the Product Description link for an item in our online catalog. (View USP's policy statement on [\(1\) Certificates of Analysis for USP Reference Standards](#)  (62KB), or read our [\(2\) Document Disclosure Policy](#).)

What is the specific purity of individual USP Reference Standards?

Unless otherwise specified on the label, all USP Reference Standards are 100.0% pure for compendial use in quantitative applications. The USP Catalog contains the labeled values for every current lot. These labeled values are intended for only specific quantitative USP–NF applications. For more information, contact RS Technical Service at rstech@usp.org.

How do USP units convert to International Units?

USP Endotoxin units are identical to International Units. Relationships for other USP Reference Standards must be determined on a case-by-case basis. If you need help, call 1–800–227–8772 or +1–301–881–0666 and ask to speak to a scientific staff member.

Why is the catalog number on my Reference Standard different than others, and will that affect its compendial use?

In July 2002, USP decided to improve the numbering system for all of our Reference Standard products. USP added a "1" as the first digit of the item number and removed the "-"punctuations. For example

| Item | Old Item No. | New Item No. |
|----------------------------------|--------------|--------------|
| Acetaminophen (400 mg) | 00300–9 | 1003009 |
| Brompheniramine Maleate (125 mg) | 07800–8 | 1078008 |

The item numbers on labels of USP products were not changed until the next lot was available for each product. Based on inventory levels and demand for each Reference Standard, the change process could take as long as five to seven years to complete.

There is no correlation between the labels or item numbers from the old numbering system and the potency, stability, or suitability for use of USP Reference Standards. USP monitors items in our inventory on a regular basis.