

Frequently Asked Questions

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Certified Reference Materials

What is a USP Certified Reference Material (CRM)?

A USP Certified Reference Material (CRM) is a USP Reference Standard with a "pedigree." It should be used as a USP Reference Standard. A CRM is a special class and the next generation of a USP Reference Standard that has undergone additional metrologically based testing and statistical analysis. The USP CRM is issued with a Certificate of Analysis (COA), listing a certified property value with its associated uncertainty, expiration date, and other information, according to ISO Guide 31[1]. The one or more property values are certified by a procedure that establishes its traceability to an accurate realization of the unit in which the property values are expressed [2].

How do I use a CRM?

Since a USP CRM is a USP Reference Standard, it should be used in the same way in which you would use a USP Reference Standard. The user should follow the current monograph and label instructions. What should I do with my past and future results, if I am a current purchaser of a USP Reference Standard that has now become a USP CRM?

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Nothing needs to be done concerning past and future results, since a CRM is also a Reference Standard. A measurement uncertainty may be calculated using information from the USP COA and your experimental data, if appropriate.

What should I do about the uncertainty of my house standard, if I use the USP Reference Standard to make the house standard?

You may propagate the uncertainty of your house standard using the standard uncertainty of the USP CRM [3, 4].

Why is USP authorized to produce CRMs?

USP is ISO Guide 34 accredited as a Reference Material producer (RMP) of Chemical CRMs.

Why is USP producing CRMs?

USP is the first global pharmacopeia to produce CRMs to meet the increasingly demanding measurement needs of the industry. USP has always produced quality reference materials and the CRMs are a further improvement in the final product by advancing the metrological science of our Reference Standards. The purpose of the CRMs is to provide a higher degree of confidence in the analytical measurement that leads to decisions regarding product specification and acceptance limits.

What are the benefits of a USP CRM?

A USP CRM is a means to establishing trueness and traceability to the measurement system, thereby allowing and enabling consistency and comparability of measurements and results over periods of time and among laboratories. Traceability and uncertainty of measurement are important components in the documentation for ISO 17025 requirement for testing labs.

What do I do with the certificate? What do I do with the certified property value and the uncertainty value?

The CRM COA provides confidence in the property value(s), measurement traceability, and internal and external quality assurance. The CRM certified property value may be used for calibration, comparison, or value assignment. The CRM user is able to propagate uncertainty to the final result, and is able to make meaningful comparisons of measurement results.

Is there a difference between acceptance criteria and certified property value and uncertainty (CRM)?

The acceptance criteria and certified property value and uncertainty (CRM) are completely different concepts derived from different principles. The CRM provides trueness of measurement, an assigned value and how far from that value the actual value can be with a stated level of confidence. The monograph limits are specified in the appropriate USP–NF monograph. Acceptance criteria are determined by the customer. The CRM contributes neither to the product specification nor the acceptance criteria. The proper implementation and integration of a CRM into the measurement process lends assurance the specifications and acceptance criteria are met.

Does the USP CRM cost more than the USP Reference Standard?

Initially, the price of the USP CRM will be the same as the USP Reference Standard. This improvement in the final product is presently an additional bonus to your purchase at USP Reference Standard prices.

How many more USP CRMs will be available for purchase?

USP is committed to producing CRMs, and you can expect to find more available to purchase each year.

What if the COA is lost or removed from the packaging?

A copy of the certificate is available on the Reference Standards [Web site listings](#); select the CRM name and then click on "View" next to "USP Certificate."

May I buy just the USP RS without the certificate?

If the CRM is available, the reference material will be sold only as a CRM.

Why does a USP CRM have an expiration date (period of validity) and what does the expiration date mean?

The expiration date (period of validity) of a CRM is required by ISO Guide 31 [1]. The CRM property value and uncertainty is applicable to the unopened vial for the stated period of validity. It is expected that the USP Reference Standard will be used when opened. USP generally provides enough material for multiple preparations. Any unused portions remaining after the container has been opened should be carefully stored in accordance with prudent laboratory procedures. Many variables are outside of the control of USP. Therefore, USP makes no warranties concerning the continued suitability of previously opened Reference Standards, hence CRMs. Decisions concerning the proper use of previously opened Reference Standards are the responsibility of the purchaser.

If a CRM/Reference Standard lot is exhausted, which expiration date should be used, the valid use date of the Reference Standard/CRM lot or the COA period of validity?

If a CRM/Reference Standard lot is exhausted, the earlier date takes precedence. For example, if the valid use date of a USP Reference Standard/CRM is September 2009 and the CRM COA is September 24, 2010, the valid use date of September 2009 should be used. The date that comes first (valid use date or period of validity) always takes precedence. The CRM certified property value is valid for the stated period of validity on the CRM COA. If the valid use date comes before the CRM COA period of validity and the valid use date has past, the material is no longer a Reference Standard and cannot be used for official compendial uses. FDA requirements for an official Reference Standard would not be met. However, the material may be used as a CRM (i.e., check standard).

References