

November 01, 2020

Effective: November 01, 2020, until superseded

Subject: USP Reference Standard Certificates and Assigned Values

Dear Valued USP Customer:

USP does not provide Certificates of Analysis (COAs) for USP Reference Standards (RS). USP does provide USP Certificates for most USP RS's. USP Certificates do not completely describe the test results obtained during evaluation. Rather, they are issued to provide users with information such as a hard copy of the USP RS label text, molecular information, typical chromatograms (limited cases), and additional use/handling information that may not be contained on the RS label.

USP Certificates for current and previous lots, when available, can be viewed on our website by clicking on the Product Description of the RS in the <u>online USP store</u>. This product page in the online store can also be accessed by clicking on the catalog number of the RS in the <u>USP Reference Standards Catalog</u>. If there is not a link to view the USP Certificate for a specific lot number, then a USP Certificate is not available for that lot.

The assigned value of a USP RS is provided on the label and/or the USP Certificate of a particular lot. Assigned values are not provided for RS's developed only for qualitative use in USP compendial procedures. A statement such as "Labeled for Qualitative Use" may also be included on the label. A value of 100.0% cannot be assumed for any USP RS without an assigned value included on its label and/or USP Certificate. If an assigned value is not provided, then the particular lot was not developed for quantitative use.

All information required for the official use of a USP RS is provided in the associated USP compendial procedure, the label of the RS, and on its USP Certificate, if available. Test results and data that are not included in these sources cannot be shared as they are considered proprietary to the USP Reference Standard program.

Regards,

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