Effective: August 09, 2017, until superseded

Subject:  USP Reference Standard’s Uses and Applications

Dear Valued USP Customer,

USP Reference Standards are not for use in humans or animals as drugs or medical devices. They are intended for test and assay use only as per their associated USP compendial application(s). You may be able to use USP Reference Standards for analytical or laboratory applications other than these applications but the user is responsible for determining the suitability of the standards for the non-compendial purposes. All available instructions for the intended use(s) are provided in the associated USP compendial application(s), the label of the USP Reference Standard and in its USP Certificate, if available.

A USP Reference Standard, where explicitly mentioned in an official USP compendial monograph, is considered to be part of the official method. In the event of a dispute, it is the USP monograph with its associated USP Reference Standard(s) which determines compliance. USP cannot comment on the use of a secondary standard in place of the USP Reference Standard (primary standard) specified in a USP compendial monograph.

USP’s Reference Standards are considered primary standards, except for certain biological USP Reference Standards with units of activity that are established against and traceable to the World Health Organization International Standards. USP does not develop secondary reference standards against its own primary reference standards. USP does not provide guidance on the qualification or use of such secondary reference standards and cannot comment on their use in place of the USP Reference Standard (primary standard) specified in a USP compendial monograph. For questions about the use of primary vs. secondary reference standards and implications for compliance, users are advised to consult with the regulatory authority where their products are marketed for guidance.

Regards,

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