



U.S. Pharmacopeia
The Standard of QualitySM

June 15, 2005

Subject: Certificate of Analysis Policy Statement for USP Reference Standards

Dear Valued USP Customer:

The United States Pharmacopeial Convention, Inc. (USP) generally does not provide certificates of analysis for USP Reference Standards, as outlined in our Document Disclosure Policy (<http://www.usp.org/aboutUSP/governance/policies/documentDisclosure.html>). This is done for scientific and legal reasons. USP Reference Standards are provided for use in the tests and assays of the official methods of the USP. For quantitative test purposes, they are to be utilized at a value of 100%, unless specifically labeled otherwise.

The materials proposed for use as official USP Reference Standards are subjected to collaborative study. The resultant data profile is formally submitted to the USP Reference Standards Committee, the volunteer body that ultimately passes judgment on the suitability of the candidate for the intended official application(s). Once the USP Reference Standards Committee unanimously approves the material, the product is packaged, labeled, and checked for quality control before being released for distribution.

Please note, as indicated above, USP Reference Standards are intended for use in the official methods found in the current *USP-NF*. Determination of the appropriateness of USP Reference Standards for non-official use is the responsibility of the user. USP Reference Standards are not intended for administration to humans or animals as drugs or medical devices. They are intended for Test and Assay Use only. Please refer to Chapter <11> in the current version of the *USP-NF* for further information.

USP Reference Standards are not labeled with an expiration date, because USP uses an “official lot system.” This system provides greater control and flexibility in responding to revisions in the Reference Standard usage than an expiration dating system. It allows USP to control or limit the period of a lot based on analytical testing or advance in methods of analysis. USP updates and publishes the official lot and previous lot valid use date for each Reference Standard in the *Official USP Reference Standards Catalog*. Additionally, this information can be found in the *Pharmacopeial Forum* and the online Reference Standards catalog located at www.usp.org.

Best regards,

A handwritten signature in black ink, appearing to read 'Keith Conerly', written in a cursive style.

Keith Conerly
Director, Quality Assurance

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