



U.S. Pharmacopeia
The Standard of QualitySM

April 1, 2009

Subject: Certificate of Analysis 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. 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 *United States Pharmacopeia-National Formulary (USP-NF)*. 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 approves 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.

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Regards,

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