



U.S. Pharmacopeia
The Standard of Quality™

April 30, 2008

RE: Annual Recertification not required for USP Near IR System Suitability RS

Dear Valued USP Customer:

The USP Near Infrared System Suitability RS does not require recertification due to the following:

- 1. The component material** – The reference standard is composed of a mixture of three rare earth oxides—dysprosium, holmium, and erbium—plus talc, each having intrinsic properties.
- 2. A proprietary housing and seal** – The materials have been pressed into housing with an improved mechanical seal that mitigates moisture exposure - a known cause of peak shifts.
- 3. USP's continuous suitability for use program** – The reference standard follows a lot system similar to that of all other USP Reference Standards. The reference standard was tested during collaborative tests that established its suitability for use and reproducibility. USP is conducting a continuous suitability for use program to ensure that any lot will be suitable for use as indicated in the USP-NF. USP will inform customers at any point a lot is deemed to be no longer suitable for the intended use.

Although not required by USP, a user of the USP Near Infrared System Suitability RS may choose to verify the USP-assigned peak positions under GLP or GMP guidelines. The decision to verify and the frequency of verification are determined by the user.

To determine the status of any Reference Standard, please consult the Official USP Reference Standards catalog, published bimonthly as a stand alone document or found on the USP Website at <http://www.usp.org/products/referenceStandards/>.

Sincerely,

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