



U.S. Pharmacopeia
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Greater Certainty in Monitoring Three Therapeutic Medications is Facilitated by New USP Certified Reference Materials

*Materials Advance State-of-the-Art Pharmaceutical Testing,
Respond to Needs of In-Vitro Drug Device Industry*

Rockville, Md., November 18, 2009 — To help bring greater certainty to the measurement of medication levels in a patient's bloodstream for three drugs with narrow therapeutic ranges, the U.S. Pharmacopeial Convention (USP) is releasing new certified reference materials (CRMs).

The three new CRMs are for carbamazepine, an anticonvulsant and mood stabilizing drug used primarily in the treatment of epilepsy and bipolar disorder; phenytoin, commonly used as an antiepileptic; and theophylline, used in the treatment of respiratory diseases. These three drugs are among a group of medicines that are often monitored in the bloodstream of patients that have been prescribed the drugs. Such medicines may need to be carefully monitored for a number of reasons, including a narrow therapeutic range or risk of toxicity. Therapeutic drug monitoring may also be necessary for drugs that are intended to maintain the absence (as opposed to the presence) of a medical condition, such as seizures.

CRMs represent an important step forward for USP reference standards, which are the physical materials used to demonstrate compliance to written USP standards designating a medicine and its ingredients' identity, quality, purity, strength and consistency. CRMs are reference standards accompanied by a certificate of analysis. A CRM is rigorously tested for one or more chemical or physical properties (such as purity). A property value with associated uncertainties certified to be true based on these tests is assigned to the CRM after a thorough statistical treatment of the data. The path of metrological traceability, which provides information on how the measurement was made and which standards were used to support the measurement, is included in the Certificate of Analysis, as well as the estimated level of uncertainty associated with the assigned value. This added information regarding uncertainties and traceability is provided for users of the reference materials. Procedures for determining compliance with USP compendial quality standards remain unchanged since, as stated on the Certificates of Analysis, the associated uncertainties are not used as part of the calculation value for quantitative *USP-NF* applications.

The new CRMs will be used by the *in vitro* diagnostic device industry, which manufactures medical devices that examine specimens derived from the human body (e.g., blood or tissue donations) to provide information related to a physiological or pathological state or to monitor therapeutic measures. Requirements in Europe state that all measurements should be traceable to standards of a "higher metrological order," that is, more certain measurements. The International Organization for Standardization (ISO) states that, where possible, such standards should be CRMs. USP is the first global pharmacopeia to be ISO-certified as a producer of chemical CRMs.

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“In releasing these three new CRMs, USP is meeting the needs of the multi-national *in vitro* diagnostic device industry,” said William Koch, Ph.D., USP’s chief metrology officer. “For these three products, a higher degree of certainty in measurement is extremely important. In Europe specifically, regulations support use of CRMs for *in vitro* diagnostic devices. However, this is useful for manufacturers of these medicines worldwide.”

For more information about CRMs, visit www.usp.org/referenceStandards/CRM.html.

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USP—Advancing Public Health Since 1820

The United States Pharmacopeial Convention (USP) is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are recognized and used worldwide. For more information about USP visit <http://www.usp.org>. **FY1018**