



U.S. Pharmacopeia
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Patient Safety Advanced by Revised Heparin Standards

International Workshop Assesses Revisions Aimed at the Purity, Quality of Blood Thinner

Rockville, Md., July 30, 2009 — Continuing to help ensure the identity, purity and quality of heparin, the U.S. Pharmacopeial (USP) Convention has revised written and physical standards for the widely used blood thinner. In February, USP released updated heparin standards at the request of the Food and Drug Administration (FDA) in response to the 2008 public health crisis in which more than 200 people died as a result of heparin adulterated for economic gain. A second phase of revisions is reflected in the newly posted standards. These developments and new information about heparin were discussed by scientists and regulators at the third International Heparin Workshop held at USP headquarters in Rockville, Maryland, July 27–28.

“While financially-motivated adulteration of medicines is a distressingly persistent problem,” noted Roger L. Williams, M.D., USP’s chief executive officer, “I’m pleased at the progress we’ve made in helping to ensure that such tragic events are minimized. Stronger methods for detecting a range of potential contaminants have been thoroughly assessed and incorporated into the new test methods, and the new physical reference standards are specific to these methods. Manufacturers—and in consequence, physicians and their patients—can feel more confident of the purity and integrity of their heparin products.”

The Workshop, co-sponsored by USP, the British National Institute of Biological Standards and Control (NIBSC), and the European Directorate for the Quality of Medicines (EDQM), reflected the global nature of both the problem of adulteration and the resources cooperating to combat it, with attendees from more than 17 countries.

The updated written standards are the Heparin Sodium Stage 2 Monograph and the Heparin Sodium Injection Stage 2 Monograph; new reference standards are Heparin Sodium for Assays, Oversulfated Chondroitin Sulfate, and Dermatan Sulfate. These and other related standards and information are available at <http://www.usp.org/hottopics/heparin.html>. The new standards will become official on October 1, 2009.

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USP—Advancing Public Health Since 1820

The United States Pharmacopeial (USP) Convention 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>. **FY1004**

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