

USP statement on heparin potency unit assignment and harmonization with the International Standard for unfractionated heparin

In response to the heparin adulteration crisis of 2007/2008, USP has worked swiftly to improve the standards for unfractionated heparin (UFH) in order to secure the supply of safe heparin and heparin products in the US.

As part of the Stage 2 revisions to the Heparin Sodium monograph, USP has adopted a new potency assay for heparin, the chromogenic anti-Factor IIa test. The high specificity of this assay provides an additional safeguard against potential adulterants that may display heparin-like activity in the previous USP plasma-based assay. Transition to the new assay and parallel introduction of a new potency reference standard, USP Heparin Sodium for Assays Reference Standard, has given the USP the opportunity to calibrate the new material relative to the International Standard (IS) for UFH issued by the World Health Organization (WHO).

Over the past 30 years, there has been an estimated drift of 10% between the USP heparin unit and the international unit for UFH. The calibration of the new USP Heparin Sodium for Assays Reference Standard eliminates this difference since the standard is directly traceable to the 5th IS for UFH.

USP does not anticipate that the change in the USP heparin unit resulting from its harmonization with the IS has clinical significance. Due to the inherently low and extremely variable bioavailability of heparin, finished drug product potencies are generally specified with $\pm 10\%$ of the potency values. In addition, therapeutic dosing of heparin is generally monitored by aPTT. However, USP encourages industry stakeholders to work closely with the Food and Drug Administration and the medical community in communicating the change in potency assignment.

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