

[USP Announces a Revised Monograph For Levothyroxine Sodium Tablets](#)

Type of Posting: General Announcement

Posting Date: 29–Aug–2008

Official Date: 03–Oct–2009

USP revised the monograph for Levothyroxine Sodium Tablets, to support the action of the U.S. Food and Drug Administration to ensure the drug product retains its potency over its shelf life. USP published the revision to the Assay range in Pharmacopeial Forum 34(1) [Jan–Feb 2008] for public review and comment; the comment period ended on April 15, 2008. The proposed revision was approved for adoption by the relevant USP Expert Committee for inclusion in *USP 32–NF 27* to be published in November 2008. The revision will narrow the assay acceptance criteria from the current requirement "not less than 90.0 percent and not more than 110.0 percent of the labeled amount of levothyroxine sodium" to "not less than 95.0 percent and not more than 105.0 percent of the labeled amount of levothyroxine sodium." The change will help improve the quality of the product so that consumers receive the level of medication needed to treat their thyroid disorders. Levothyroxine Sodium Tablets are used to treat underactive thyroid glands and other thyroid conditions. Levothyroxine sodium products are used by over 13 million patients.

On October 3, 2007, FDA notified the holders of approved NDAs and ANDAs for levothyroxine sodium drug products that it will require all approved levothyroxine sodium drug products to meet a 95.0 percent to 105.0 percent range of label claim throughout their labeled shelf-lives. The manufacturers should begin meeting these specifications no later than 24 months after the notification. This proposal is part of the FDA's ongoing effort to address concerns about the performance of approved levothyroxine sodium products and to help ensure that levothyroxine sodium drug products maintain their quality throughout their shelf-lives. The FDA letter to the USP and additional information about the FDA proposal is available on the following FDA Center for Drug Evaluation and Research (CDER) website: <http://www.fda.gov/Drugs/default.htm>.

The tightened assay range in the USP monograph for Levothyroxine Sodium Tablets will become official on October 3, 2009, to correspond to the date provided by the FDA to the application holders. In this way, implementation of the USP monograph revision will be contemporaneous with the date when all FDA-approved products will be expected to meet the revised potency specifications.

Please direct any comments or questions related to the revision to Dr. Elena Gonikberg, Senior Scientist (eg@usp.org or 301-816-8251).