Levothyroxine Sodium Tablets

Type of Posting: Notice of Intent to Revise

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Expert Committee: Chemical Medicines Monographs 3

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 3 Expert Committee intends to revise the Levothyroxine Sodium Tablets monograph.

Comments were received that indicate that a small amount of liothyronine in USP Levothyroxine RS may affect the results obtained for the Limit of Liothyronine Sodium test. The Expert Committee proposes to revise this test, to perform the quantitation using a new Liothyronine standard solution containing USP Liothyronine RS only.

It is anticipated that the proposed revision will be published as an Interim Revision Announcement (IRA) in Pharmacopeial Forum 42(2) [Mar.–Apr. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on May 1, 2016. In the absence of any adverse comments the proposed IRA will become official on September 1, 2016. Should you have any questions, please contact Elena Gonikberg, Ph.D., Scientific Liaison to the Chemical Medicines Monographs 3 Expert Committee (301-816-8251 or eg@usp.org).