Methylphenidate Hydrochloride Extended-Release Tablets

Type of Posting: Notice of Intent to Revise

Posting Date: 26–Jun–2015

Targeted Official Date: Interim Revision Announcement, 01–Mar–2016

Expert Committee: Monographs—Small Molecules 4

In accordance with section 7.05(c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 4 Expert Committee intends to revise the Methylphenidate Extended-Release Tablets monograph.

Comments with supporting data were received that indicate the current *Assay* procedure is not suitable for all approved drug products. The Expert Committee has proposed to revise the Methylphenidate Hydrochloride Extended-Release Tablets monograph to replace the existing HPLC procedure for the *Assay* with a procedure based on the existing test for *Organic Impurities*, which should be suitable for all approved drug products and does not require an internal standard.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in Pharmacopeial Forum PF 41(5) [Sep.–Oct. 2015] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on November 30, 2015. In the absence of any adverse comments the proposed IRA will become official on March 1, 2016.

Should you have questions, please contact Ravi Ravichandran, Ph.D., Principal Scientific Liaison to the Monographs—Small Molecules 4 Expert Committee (301-816-8330 or rr@usp.org).