Paroxetine Hydrochloride

Type of Posting: Notice of Intent to Revise
Posting Date: 02–Jan–2019
Targeted Official Date: 01–Sep–2020, Interim Revision Announcement
Expert Committee: Chemical Medicines Monographs 4

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 4 Expert Committee intends to revise the Paroxetine Hydrochloride monograph.

The Expert Committee proposes to revise the test for *Limit of 1-Methyl-4-(p-fluorophenyl)-1,2,3,6-tetrahydropyridine*, as follows:

- Update the test name to *Limit of Paroxetine Related Compound E* consistent with current USP style.
- Replace the standard solution prepared using USP Paroxetine Related Compound E Mixture RS, which is a quantitative mixture of paroxetine related compound E in a paroxetine hydrochloride matrix, with a standard solution prepared using a new single-component reference standard of paroxetine related compound E.
- Update the chromatographic system, mobile phase, and sample and standard solution concentrations in order to improve method reliability and sensitivity. All proposed changes are based on validated methods of analysis.

Additional changes to improve the flexibility of the monograph and to align it with current USP style are also proposed.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 46 (2) [Mar.–Apr. 2020] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on May 31, 2020. In the absence of any adverse comments the proposed IRA will become official on September 1, 2020.

Should you have any questions, please contact Nicholas Garito, Scientific Liaison (301–816–8321 or njg@usp.org).
