Pimozide Tablets

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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 Pimozide Tablets monograph which appears in *USP 39–NF 34*.

Comments with supporting data were received that indicate the current analytical procedure used in *Dissolution* test should be revised. The current analytical procedure uses chloroform to extract the drug substance from the dissolution sample for analysis by UV-Vis. The Expert Committee proposes to revise the Pimozide Tablets monograph to replace the existing UV-Vis procedure used in the *Dissolution* test with a HPLC procedure based on validations performed with Phenomenex Prodigy ODS(3) brand of L1 column.

In addition the following changes will be proposed in the revision:

- The *Identification A* test, based on the infrared absorption, is revised to allow more flexibility to the users.
- The limit for any individual unspecified degradation product will be widened from NMT 0.5% to NMT 1.0% to be consistent with FDA approved limits.
- The limit of Total degradation products widened from NMT 0.75% to NMT 2.0% to be consistent with FDA approved limits.

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacopeial Forum* 42(3) [May–Jun. 2016] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July 31. 2016. In the absence of any adverse comments the proposed IRA will become official on November 1, 2016.

Should you have questions, please contact K. Kalyana Seela, Senior Scientific Liaison to the Chemical Medicines Monographs 4 Expert Committee at kks@usp.org.