Pyridostigmine Bromide Tablets

Type of Posting: Notice of Intent to Revise

Posting Date: 30–Dec–2016

Targeted Official Date: 01–Sep–2017, 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 Pyridostigmine Bromide Tablets monograph.

The Expert Committee proposes to revise the limits for specified and total impurities in the Organic Impurities section to be consistent with FDA approved acceptance criteria.

- The limit for pyridostigmine related compound A will be revised from NMT 0.4% to NMT 0.2%
- The limit for pyridostigmine related compound B will be revised from NMT 6% to NMT 0.2%
- Total of unspecified degradation products will be revised to Total degradation products and the acceptance criteria will be changed from NMT 0.4% to NMT 0.5%

It is anticipated that the proposed revision will be published as a proposed Interim Revision Announcement (IRA) in *Pharmacopeial Forum* PF 43(2) [Mar.–Apr. 2017] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on May 31, 2017. In the absence of any adverse comments the proposed IRA will become official on September 1, 2017.

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