Tamsulosin Hydrochloride

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 Tamsulosin Hydrochloride monograph.

Based on the comments received, the Expert Committee proposes to make the following changes under the Assay to improve reproducibility of the chromatographic procedure:

- Increase the concentration of the Standard solution and the Sample solution to 0.5 mg/mL, to improve the response of the analyte
- Change the Diluent to a mixture of acetonitrile and water (20:80), to increase similarity to the Mobile phase composition
- Change column temperature to 35°, to improve peak shape.

In addition, the *Identification A* test, based on the infrared absorption, is revised to allow more flexibility to the users.

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).