Dutasteride

Type of Posting: Notice of Intent to Revise

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

Expert Committee: Monographs—Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Monographs—Small Molecules 4 Expert Committee intends to revise the Dutasteride monograph as follows.

- Move dihydrodutasteride from Organic Impurities, Procedure 1 to Organic Impurities, Procedure 2. Add the relative response factor, 0.38, for the impurity.
- Change the resolution between the dutasteride ?-dimer and dutasteride ?-dimer peaks in the Procedure 2 Suitability Requirements from NLT 2.0 to NLT 1.5.
- Remove redundant text from the Limit of quantitation section under Limit of Platinum and changed platinum to Dutasteride in the definition of Cs.
- Remove the Standard solution from the Organic Impurities section, as it is not used.
- Clarify the procedure in Water Determination so it corresponds to that used by the sponsor.
- Clarify the listing of the USP Dutasteride Resolution Mixture RS contents to indicate that it includes dutasteride.

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 any questions, please contact David A. Porter, Ph. D. (240-221-2088 or ddp@usp.org).