

Tamsulosin Hydrochloride Capsules

Type of Posting: Notice of Intent to Revise

Posting Date: 30-Apr-2010

Official Date: Revision Bulletin, Date To Be Determined

Expert Committee: Monograph Development—Gastrointestinal, Renal and Endocrine

In accordance with section 9.05(c) of the Rules and Procedures of the 2005–2010 Council of Experts, the Monograph Development—Gastrointestinal, Renal and Endocrine Expert Committee intends to revise the monograph for Tamsulosin Hydrochloride Capsules, to accommodate new approved products. Comments were received that the Sample preparation under Identification-A, the Assay preparation under the Assay, and the Test solution under the Uniformity of dosage units in the current monograph are not suitable for certain formulations. The Expert Committee intends to add alternative preparations to the Identification-A, Assay, and Uniformity of dosage units using a flexible monograph approach.

It is anticipated that the proposed revisions will be published as a Revision Bulletin pursuant to section 9.02(d) of the Rules and Procedures.

Should you have questions, please contact Elena Gonikberg, Ph.D., Scientific Liaison to the Monograph Development—Gastrointestinal, Renal and Endocrine Expert Committee (301-816-8251 or eg@usp.org).