Norethindrone Acetate and Ethinyl Estradiol Tablets

Type of Posting: Notice of Intent to Revise

Posting Date: 30–Jul–2010

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Expert Committee: Monographs—Small Molecules 4

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 4 Expert Committee intends to revise the Norethindrone Acetate and Ethinyl Estradiol Tablets monograph based on a submission from an approved manufacturer. Reflecting USP's monograph modernization efforts, revision of several procedures will be proposed, however no changes to limits or acceptance criteria are planned. The revision includes replacing the two UV spectrophotometric Assay procedures with a single stability-indicating HPLC procedure. Due to the change of the Assay procedure, changes will also be proposed for the Identification and Uniformity of Dosage Units sections of the monograph.

The proposed revisions will be published as In-Process Revision in Pharmacopeial Forum (PF) 36(5) [Sep–Oct 2010]. The comment deadline for this proposal will be December 15, 2010.

Should you have questions, please contact Mary Waddell, Scientific Liaison to the Expert Committee (301-816-8124 or msw@usp.org).