Estradiol and Norethindrone Acetate Tablets

Type of Posting	Revision Bulletin
Posting Date	18–Nov–2016
Official Date	01–Dec–2016
Expert Committee	Chemical Medicines Monographs 5
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015-2020 Council of Experts, the Chemical Medicines Monographs 5 Expert Committee has revised the Estradiol and Norethindrone Acetate Tablets monograph. The purpose for the revision is to add *Dissolution Test* 2 to accommodate the FDA approved specifications for the sponsor product. The labeling information is also incorporated to support the inclusion of *Dissolution Test 2.*

- *Dissolution Test 2* was validated using Zorbax Eclipse XDB-C18 brand of L1 column. The typical retention times for estradiol and norethindrone acetate are about 3.0 min and 9.5 min respectively.

Additionally, minor editorial changes have been made to update the monograph to current USP style.

The Estradiol and Norethindrone Acetate Tablets Revision Bulletin supersedes the currently official monograph. The Revision Bulletin will be incorporated in the *Second Supplement* to *USP 40–NF 35*.

Should you have any questions, please contact Sridevi Ramachandran, PhD., Associate Scientific Liaison (sdr@usp.org) or Gerald Hsu, PhD., Senior Scientific Liaison (gdh@usp.org).