Raloxifene Hydrochloride Tablets

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Expert Committee: Monographs—Small Molecules 4

Reason for Revision: Compliance

In accordance with the Rules and Procedures of the 2010-2015 Council of Experts, the Monographs- Small Molecules 4 Expert Committee has revised the Raloxifene Hydrochloride Tablets monograph. The purpose for the revision is to add Dissolution Test 2 for a drug product approved by the FDA.

The liquid chromatographic procedure used in Dissolution Test 2 is based on analyses performed with a Symmetry C18 brand of L1 column manufactured by Waters. The typical retention time for raloxifene is about 3 minutes.

In addition, an alternative sample preparation is included for Identification test A to exclude interference of excipients from a different formulation.

The Raloxifene Hydrochloride Tablets Revision Bulletin supersedes the currently official monograph. The Revision Bulletin will be incorporated in *USP 39–NF 34*.

Should you have any questions, please contact Mary P. Koleck, Ph.D. (301-230-7420 or mpk@usp.org).

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