Raloxifene Hydrochloride Tablets

Type of Posting: Revision Bulletin

Posting Date: 27-Mar-2015

Official Date: 01-Apr-2015

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).

Download the Raloxifene Hydrochloride Tablets Revision Bulletin