

Risedronate Sodium Delayed-Release Tablets

Type of Posting Revision Bulletin
Posting Date 26-Apr-2024
Official Date 1-May-2024

Expert Committee Small Molecules 3

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 3 Expert Committee has revised the Risedronate Sodium Delayed-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 2* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Existing references to reagents and reagent names have been updated for consistency with official reagent entry names. *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2*.

• Dissolution Test 2 was validated using the XTerra RP18 brand of column with L1 packing. The typical retention time for risedronate is about 7.5 min.

The Risedronate Sodium Delayed-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Yanyin Yang, Senior Scientist II (301-692-3623 or yanyin.yang@usp.org).