



Ketoconazole Tablets

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Expert Committee	Small Molecules 1

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 1 Expert Committee has revised the Ketoconazole 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). *Labeling* information has been incorporated to support the inclusion of *Dissolution Test 2*. Additionally, minor editorial changes have been made to update the monograph to current *USP* style. Existing references to reagents have been updated for consistency with the reagent entry.

- *Dissolution Test 2* was validated using the MicroBondapak C18 brand of column with L1 packing. The typical retention time for ketoconazole is about 6 min.

The Ketoconazole Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Jasmine Lawrence, Scientist III (301-230-6363 or jasmine.lawrence@usp.org).