



Quetiapine Extended-Release Tablets

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Expert Committee	Small Molecules 4

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 4 Expert Committee has revised the Quetiapine Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 9* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). The revision also necessitates a change in the table numbering in the *Assay* and the *Organic Impurities* test.

- *Dissolution Test 9* was validated using the Sunfire C18 brand of column with L1 packing. The typical retention time for quetiapine is about 4.7 min.

The Quetiapine Extended-Release Tablets Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Tsion Bililign, Principal Scientist (301-816-8286 or tb@usp.org).