Quetiapine Extended-Release Tablets

Type of Posting	Revision Bulletin
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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 13* and *Dissolution Test 14* 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 test for *Organic Impurities*.

- *Dissolution Test 13* was validated using the Hypersil BDS C8 brand of column with L7 packing. The typical retention time for quetiapine is about 4 min.

- *Dissolution Test 14* was validated using the Phenomenex Luna C8 100A brand of column with L7 packing. The typical retention time for quetiapine is about 2.2 min.

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

Should you have any questions, please contact V. Durga Prasad, Senior Scientist II (91-40-4448-8723 or durgaprasad.v@usp.org).