Quetiapine Extended-Release Tablets

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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 12 to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s). Clarifications/updates have been included in the preparation of the 0.05 M phosphate buffer solution, Buffer stage medium, and Acid stage sample solution in Dissolution Test 12. The revision also necessitates a change in the table numbering in the test for Organic Impurities.

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.