Lamotrigine 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 Lamotrigine 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 test for *Organic Impurities*. Existing references to reagents have been updated for consistency with the reagent entry.

- *Dissolution Test 9* was validated using the Discovery HS C18 brand of column with L1 packing. The typical retention time for lamotrigine is about 3 min in the *Acid stage* and about 2 min in the *Buffer stage*.

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

Should you have any questions, please contact Robyn Fales, Senior Scientist I (240-221-2047 or rnp@usp.org).