Lamotrigine Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	28-Jun-2024
Official Date	1-Jul-2024
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 10* and *Test 11* to accommodate FDA-approved drug products with different dissolution conditions and/or tolerances than the existing dissolution test(s).

Additionally, *Dissolution Test 9* is revised to accommodate FDA-approved drug products of different strengths by adding the tolerances for 300-mg tablets and updating the tolerances for 250-mg tablets. These revisions also necessitate a change in the table numbering in the test for *Organic Impurities*.

- *Dissolution Test 10* was validated using the Xterra RP18 brand of column with L1 packing. The typical retention time for lamotrigine is about 2.5 min.

The Lamotrigine 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).