

Lamotrigine Extended-Release Tablets

Type of Posting	Revision Bulletin
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Official Date	01–May–2018
Expert Committee	Chemical Medicines Monographs 4
Reason for Revision	Compliance

In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Chemical Medicines Monographs 4 Expert Committee has revised the Lamotrigine Extended-Release Tablets monograph. The purpose for the revision is to add *Dissolution Test 5* to accommodate drug products that were approved with different dissolution conditions and acceptance criteria. The revision necessitates a change in the table numbering in the *Organic Impurities* section.

- *Dissolution Test 5* was validated using an Xterra RP18 brand of L1 column. The typical retention time for lamotrigine is about 2.5 min.

The Lamotrigine Extended-Release Tablets Revision Bulletin supersedes the currently official Lamotrigine Extended-Release Tablets monograph. The Revision Bulletin will be incorporated in *USP 42–NF 37*.

Should you have any questions, please contact Ren-Hwa Yeh, Senior Scientific Liaison (301-998-6818 or rhy@usp.org).

