

Bupropion Hydrochloride Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	26–May–2017
Official Date	01–Jun–2017
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 Bupropion Hydrochloride Extended-Release Tablets monograph. The purpose for the revision is to add dissolution tests to accommodate drug products which were approved with different dissolution conditions and acceptance criteria.

- *Dissolution Test 16* was validated using an ACE 5 C18 brand of L1 column. The typical retention time for bupropion is about 10 min.
- *Dissolution Test 17* and 18 were validated using a Symmetry C8 brand of L7 column. The typical retention time for bupropion is about 2.6 min.

The Bupropion Hydrochloride Extended-Release Tablets Revision Bulletin supersedes the currently official monograph. The Revision Bulletin will be incorporated into *USP 41–NF 36*.

Should you have any questions, please contact Heather Joyce, Ph.D., Senior Scientific Liaison (301–998–6792 or hrj@usp.org.)

