

Bupropion Hydrochloride 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 Bupropion Hydrochloride Extended-Release Tablets monograph. The purpose of this revision is to add *Dissolution Test 27* and *Dissolution Test 28* 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*.

• Dissolution Test 27 was validated using the Luna C18(2) brand of column with L1 packing. The typical retention time for bupropion is about 3 min.

The Bupropion Hydrochloride 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).