Bupropion Hydrochloride Extended-Release Tablets

Type of Posting	Revision Bulletin
Posting Date	29-Oct-2021
Official Date	1-Nov-2021
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 the revision is to add *Dissolution Test 24* 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 *Dissolution Test 25*, *Dissolution Test 26*, and the test for *Organic Impurities*. In addition, the tolerances in *Dissolution Test 1* are widened to accommodate FDA-approved drug products utilizing this dissolution test but with different tolerances than the existing test. The format of this test is updated to current *USP* technical style, including the addition of the necessary equations. Also, the acceptance criterion for “3-Chlorobenzoic acid” in the test for *Organic Impurities* is widened from NMT 0.3% to NMT 0.5% to be consistent with the FDA-approved specification.

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

Should you have any questions, please contact Nicholas Garito, Jr., Principal Scientist (301-816-8321 or njg@usp.org).