



Diltiazem Hydrochloride Extended-Release Capsules

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Expert Committee	Small Molecules 6

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 6 Expert Committee has revised the Diltiazem Hydrochloride Extended-Release Capsules monograph. The purpose of this revision is to add *Dissolution Tests 31* and *32* 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 31* was validated using the Ultramex brand of column with L7 packing. The typical retention time for diltiazem is in the range of 5–8 min.
- *Dissolution Test 32* was validated using the Inertsil ODS-3V brand of column with L1 packing. The typical retention time for diltiazem is in the range of 4–7 min.

The Diltiazem Hydrochloride Extended-Release Capsules Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Tsion Bililign, Principal Scientist (301-816-8286 or tb@usp.org).